

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/28/2020 6:54:42 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdo, Mark [Mark.Abdo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Throckmorton, Douglas C [Douglas.Throckmorton@fda.hhs.gov]; Solberg, Tim [Tim.Solberg@fda.hhs.gov]; Keller, Melanie [Melanie.Keller@fda.hhs.gov]; Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Tyler, James [James.Tyler@fda.hhs.gov]; Beach, Carter [Carter.Beach@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Malais, Tanya [Tanya.Malais@fda.hhs.gov]; Janik, Heather [Heather.Janik@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Ricci, Linda J [Linda.Ricci@fda.hhs.gov]; O'Callaghan, Kathryn [Kathryn.OCallaghan@fda.hhs.gov]; Lynch, Sarah [Sarah.Lynch@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Bess, Demetrice [Demetrice.Bess@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Caccamo, Stephanie [Stephanie.Caccamo@fda.hhs.gov]; Ross, Bruce [Bruce.Ross@fda.hhs.gov]; Torres-Rivera, Sahra [Sahra.Torres-Rivera@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]

**Subject:** COVID-19 Agency Executive Group meeting  
**Attachments:** COVID-19 Agency Executive Group meeting  
**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)

**Start:** 3/7/2020 11:15:00 AM  
**End:** 3/7/2020 11:30:00 AM  
**Show Time As:** Busy

**Recurrence:** Weekly  
every Saturday from 11:15 AM to 11:30 AM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccamo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide high-level updates on key issues and activities on their respective areas as applicable.

(b)(5)

**(b)(5)**



**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/28/2020 6:54:42 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abfb1e-KMO8]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** COVID-19 Agency Executive Group meeting

**Attachments:** COVID-19 Agency Executive Group meeting

**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)

**Start:** 3/7/2020 11:15:00 AM

**End:** 3/7/2020 11:30:00 AM

**Show Time As:** Tentative

**Recurrence:** Weekly  
every Saturday from 11:15 AM to 11:30 AM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair,

---

Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccamo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide high-level updates on key issues and activities on their respective areas as applicable.

**AEG DAILY CHECKLIST**

**(b)(5)**

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/28/2020 6:54:42 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Solberg, Tim  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea]; Cavazzoni, Patrizia  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Rebello, Heidi  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Clarke, Mary Beth  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Yiannas, Frank  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Finnen, April  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; 2019-nCoV FDA IMG  
 Planning [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Chiverton, Evan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=664891126c2f4b36a17ff06fc18ad73d-Evan.Chiver]; Measer, Gregory  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Boon, Caitlin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Aldridge, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f7761ef82074a45a6a58ac539b3dbb5-Megan.McCur]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Gutierrez, Sacha [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8490d020e45245b48335435bd64bd384-Sacha.Gutie]; Demers, Donald E [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee9abcfa1b9a4d2a9222bd5ebb733faf-DDEMERS]; Pillai, Segaran [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5e546783d4445fa315d858e0c92d47-Segaran.Pil]; Stone, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Schweitzer, Roxanne K [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Domanski, Jeffrey [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebf0a50f6cd4d7f9-Jeffrey.Dom]; Cason, Winona [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3434073fc4cc4b578c59ca60a5da91f8-Winona.Caso]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Johanson, Elaine [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]

**Subject:** COVID-19 AEG Weekend Check-in

**Attachments:** COVID-19 Agency Executive Group meeting; COVID-19 Agency Executive Group Weekend Check-in; Untitled Attachment; Untitled Attachment; Agenda\_COVID19 Meetings\_20MAR2020\_rev (002).doc

**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)

**Start:** 3/21/2020 3:00:00 PM

**End:** 3/21/2020 3:30:00 PM

**Show Time As:** Busy

**Recurrence:** Weekly  
every Sunday and Saturday from 3:00 PM to 3:30 PM

---

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Zeller, Mitchell; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Rebello, Heidi; Clarke, Mary Beth; Yiannas, Frank; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccomo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; McWilliams, Carly; 2019-nCoV FDA IMG Planning; Chiverton, Evan; Measer, Gregory; Boon, Caitlin; Edmonds, Amanda; Felberbaum, Michael; Dooren, Jennifer; Franklin, Joseph; Slikker, William; Courtney, Brooke; Sadove, Elizabeth; Aldridge, Megan; Barth, Janelle; Gutierrez, Sacha; Demers, Donald E; Pillai, Segaran; Stone, Eric; Schweitzer, Roxanne K; Huttenlocker, Denise; Hussey, Deirdre; Barfell, Glenda F; Domanski, Jeffrey; Cason, Winona; McBride, Maren; Johanson, Elaine; Raghuwanshi, Rakesh; Klimczak, Katherine

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide **brief** updates on key issues and activities on their respective areas, as applicable.

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/28/2020 6:54:42 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fecaf0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdo, Mark [Mark.Abdo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Throckmorton, Douglas C [Douglas.Throckmorton@fda.hhs.gov]; Solberg, Tim [Tim.Solberg@fda.hhs.gov]; Keller, Melanie [Melanie.Keller@fda.hhs.gov]; Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Tyler, James [James.Tyler@fda.hhs.gov]; Beach, Carter [Carter.Beach@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Malais, Tanya [Tanya.Malais@fda.hhs.gov]; Janik, Heather [Heather.Janik@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Ricci, Linda J [Linda.Ricci@fda.hhs.gov]; O'Callaghan, Kathryn [Kathryn.OCallaghan@fda.hhs.gov]; Lynch, Sarah [Sarah.Lynch@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Bess, Demetrice [Demetrice.Bess@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Caccamo, Stephanie [Stephanie.Caccamo@fda.hhs.gov]; Ross, Bruce [Bruce.Ross@fda.hhs.gov]; Torres-Rivera, Sahra [Sahra.Torres-Rivera@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; Zeller, Mitchell [Mitchell.Zeller@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; McWilliams, Carly [Carly.McWilliams@fda.hhs.gov]  
**CC:** Clarke, Mary Beth [Marybeth.Clarke@fda.hhs.gov]

**Subject:** COVID-19 Agency Executive Group Weekend Check-in  
**Attachments:** COVID-19 Agency Executive Group meeting; Canceled: COVID-19 Agency Executive Group Weekend Check-in  
**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)

**Start:** 3/7/2020 3:00:00 PM  
**End:** 3/7/2020 3:15:00 PM  
**Show Time As:** Busy

**Recurrence:** Weekly  
every Sunday and Saturday from 3:00 PM to 3:15 PM  
**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccamo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; Zeller, Mitchell; Yiannas, Frank; McWilliams, Carly

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide **brief** updates on key issues and activities on their respective areas, as applicable.

## **AEG DAILY CHECKLIST**



**(b)(5)**

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/28/2020 6:55:03 PM  
**To:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Subject:** Accepted: COVID-19 Agency Executive Group meeting  
**Location:** CALL-IN ONLY: 1-877-465-7975, code (b)(6)  
**Start:** 3/7/2020 11:15:00 AM  
**End:** 3/7/2020 11:30:00 AM  
**Recurrence:** (none)

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/28/2020 7:38:36 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Subject:** FOR URGENT REVIEW: diagnostic guidance PR  
**Attachments:** Diagnostic guidance\_draft PR\_730pm.docx  
**Importance:** High

Dr. Hahn, attached is the release ready for your review. Quote pulled out and pasted below. Standing by.

(b)(5)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/28/2020 8:36:41 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: COVID-19 Agency Executive Group meeting  
**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)  
**Start:** 2/29/2020 11:15:00 AM  
**End:** 2/29/2020 11:30:00 AM  
  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/28/2020 8:36:50 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Tentative: COVID-19 Agency Executive Group meeting  
**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)  
**Start:** 2/29/2020 11:15:00 AM  
**End:** 2/29/2020 11:30:00 AM  
  
**Recurrence:** (none)

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/28/2020 8:44:15 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group

---

**CC:** (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]

**Subject:** Updated Draft Travel Policy

**Attachments:** DRAFT FDA Travel Policy COVID-19.docx

Hi. Updated draft travel policy based on our conversation yesterday for your thoughtful consideration...realizing that the epidemic is unfolding rapidly.

Thx - m

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/28/2020 9:09:05 PM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**CC:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]  
**Subject:** RE: FOR SH Clearance OCC-CLEARED REVISED Supply chain statement tweets

Ok thx

---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Date:** February 28, 2020 at 5:13:36 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Subject:** RE: FOR SH Clearance OCC-CLEARED REVISED Supply chain statement tweets

It has been disclosed so I believe it is appropriate.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Friday, February 28, 2020 5:00 PM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Subject:** Re: FOR SH Clearance OCC-CLEARED REVISED Supply chain statement tweets

Look good. Any reason not to disclose that there is one drug shortage related to CV?

Sent from my iPhone

On Feb 28, 2020, at 4:56 PM, Caliguiri, Laura <[Laura.Caliguiri@fda.hhs.gov](mailto:Laura.Caliguiri@fda.hhs.gov)> wrote:

Sir  
Attached are tweets for your clearance. Please let me know your approval or comment. Thank you.  
Laura

**Supply Chain Tweets**  
**@SteveFDA Account**  
**Individual tweets--- To be spread out**

(b)(5)



3/1/20

2. See my update on how @US\_FDA is monitoring the supply chain of FDA-regulated products and working to mitigate shortages during the #coronavirus outbreak: [LINK TO SUPPLY CHAIN STATEMENT]

(b)(5)

2/29/20

**Thread 1—Drug shortage:**

1. FDA has been made aware of a human drug that was recently added to the drug shortages list. The manufacturer notified us that this shortage is related to a site affected by #COVID19: [the link belongs here]
2. The shortage is due to an issue with manufacturing an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients.
3. We are working with the manufacturer of this drug as well as other manufacturers to mitigate this shortage and will do everything possible to mitigate it. #COVID19
4. We have contacted over 180 human drug manufacturers to remind them of applicable legal requirements for notifying FDA of anticipated supply disruptions & to ask them to evaluate their entire supply chain, including active pharmaceuticals & other components manufactured in China.

2/29/20

**Thread 2-- PPE:**

1. We are currently not aware of specific widespread shortages of medical devices. [LINK TO SUPPLY CHAIN STATEMENT]
2. FDA has heard of increased demand & supply challenges of personal protective equipment (PPE)—gowns, gloves, surgical masks and/or respirator protective devices, or other equipment designed to protect the wearer from injury or the spread of infection or illness due to #COVID19

(b)(5)

4. We understand there are concerns about availability of PPE because of increased demand during the #COVID19 outbreak. This is not unexpected. If these supply challenges happen, we work closely with healthcare systems and local & regional health officials.

Week of 3/3/20

**Thread 3—Blood/Biologics:**

1. FDA is not aware of any cellular or gene therapies manufactured in China, and has identified no shortages of biologics as a result of supply chain disruptions from #COVID19 to report at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. The potential for transmission of #coronavirus by blood and blood components is unknown at this time; however, respiratory viruses, in general, are not known to be transmitted by blood transfusion.
3. There are no reported cases of transfusion-transmitted #COVID19.
4. The FDA has made information available to blood establishments and to establishments that manufacture human cells, tissues, or cellular or tissue-based products who may wish to consider additional donor screening measures in response to the #COVID19 outbreak.

3/2/20

**Thread 4—Animal drugs:**

1. There are 32 animal drug firms that make finished drugs in or source active pharmaceutical ingredients from China. @US\_FDA has contacted all 32 firms & currently none have reported shortages as a result of #COVID19 at this time: [LINK TO SUPPLY CHAIN STATEMENT]

2. Although none of these 32 animal drug manufacturers have reported a shortage at this time, 6 firms have indicated that there have been disruptions in the supply chain that could soon lead to shortages. FDA is working with these firms to help identify interventions to mitigate any potential shortages.

Week of 3/3/20

**Thread 5—Budget Proposal**

1. The @US\_FDA is using all our existing authorities to address #COVID19 and we welcome the opportunity to work with Congress to strengthen our #coronavirus response capabilities.

2. There are 4 specific proposals included in the President's FY 2021 budget that would better equip the agency to prevent or mitigate medical product shortages. Learn more about FDA's budget request: [LINK TO SUPPLY CHAIN STATEMENT]

**@US\_FDA Account  
Individual Tweets**

(b)(5)

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/28/2020 9:49:03 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS) [AMA2@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebdddde-HHS-Kyle.Ze]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

**Subject:** AMA WH Task Force Meeting

**Location:** WHSR JFK

**Start:** 2/29/2020 10:00:00 AM

**End:** 2/29/2020 11:00:00 AM

**Show Time As:** Busy

**Recurrence:** (none)

All,

There will be a Coronavirus Task Force Principal's Meeting tomorrow morning at 10:00am in the White House Situation Room. More details and an agenda will be forthcoming.

If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting.

WAVES Link: (b)(6)

Participants:

Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Kenneth P. Rapuano, Assistant Secretary of Defense for Homeland Defense and Global Security

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Dr. Stephen M. Hahn, Commissioner of Food and Drug Administration (FDA)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

Natalie Hurst  
Executive Assistant to the Chief of Staff  
The Office of the Vice President

(b)(6)

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/28/2020 9:49:03 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS) [AMA2@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebdddde-HHS-Kyle.Ze]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

**Subject:** AMA WH Task Force Meeting

**Location:** WHSR JFK

**Start:** 2/29/2020 10:00:00 AM

**End:** 2/29/2020 11:00:00 AM

**Show Time As:** Tentative

**Recurrence:** (none)

All,

There will be a Coronavirus Task Force Principal's Meeting tomorrow morning at 10:00am in the White House Situation Room. More details and an agenda will be forthcoming.

If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting.

WAVES Link (b)(6)

Participants:

Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Kenneth P. Rapuano, Assistant Secretary of Defense for Homeland Defense and Global Security

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Dr. Stephen M. Hahn, Commissioner of Food and Drug Administration (FDA)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

Natalie Hurst  
Executive Assistant to the Chief of Staff  
The Office of the Vice President

(b)(6)

---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/29/2020 1:18:04 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**Subject:** For Reference: Compiled FDA COVID-19 Docs 02282020  
**Attachments:** 1-26\_2019-nCoV Outbreak\_FDA SITREP\_28 February 2020.docx; 2-AEG Call Notes\_28 Feb 2020.docx; 3-SH House Update 2.28.20 925pm.docx

Attached and linked are compiled documents received on 02.28.2020 related to COVID-19 response efforts. Might be useful to have these all in one place:

- Attachment 1: [SITREP 28-Feb-2020](#)
- Attachment 2: [AEG Call Notes 28-Feb-2020](#)
- Attachment 3: [SH House Update 02.28.2020](#)

Frank

**Frank A. Olivarria**  
Management and Program Analyst  
Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: [240-402-9882](tel:240-402-9882)  
[Frank.Olivarria@fda.hhs.gov](mailto:Frank.Olivarria@fda.hhs.gov)



**From:** vinu.arumugham (b)(6)  
**Sent:** 2/29/2020 1:41:02 AM  
**To:** ljohnson (b)(6); janet.englund (b)(6); Leonard.R.Friedland (b)(6); LRFriedland (b)(6); david.greenberg (b)(6); hjanes (b)(6); kkotloff (b)(6); ofer.levy (b)(6); sarah.long (b)(6); ruth.lynfield (b)(6); pmcinnis (b)(6); asmonto (b)(6); psmg (b)(6); hanae (b)(6); mhsawyer (b)(6); Wharton, Melinda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20ac94633baa479e8282a619f083bbfb-HHS-mew2-cd]; Hunter-Thomas, Serina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd313701c7949e9935df9337c4ff635-Serina.Hunt]; rosanna.harvey@fda.hhs.gov; Slater, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2b00a57b0a747a9bc4f2317937a1022-slaterj]; Woo, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f70d0e3a7aaf442fb4962b61dde9894b-WooJ]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; CBER OCOD Consumer Account [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6d1fb37325043bcbe25183a0aaece3c-CBEROCOD]; DeStefano, Frank (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a799ec222e8741e988566e6141cbf1ba-HHS-fxd1-cd]; Thompson, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b2302812fa541759657b0569509577d-HHS-isq8-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Walker, Tanja Y (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ac93805a04cb2a742ec0845269e0f-HHS-hjn0-cd]; Secretary@HHS.gov; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissioner]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; directorsincoming@cdc.gov; francis.collins (b)(6); mrolfes1@cdc.gov; Doyle, Joshua D (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6f540756f5e4fb28f6342abb37adc80-HHS-xzd2-cd]; Blanton, Lenee H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af6c9acc0f6462e9ec15ac743cdcbc7-HHS-acy9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Tumpey, Terrence M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21ce7e7681c44913862a0b4829d19df6-HHS-tft9-cd]; Wentworth, David E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c0bcb905b046c28f7e56cd5f2c54f5-HHS-glI9-cd]; sharplessne@nih.hhs.gov; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Kretsinger, Katrina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e123d287c55c449d84c4e5dcafb80a33-HHS-kok4-cd]; Linkins, Robert (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ac11517f634867818d7a8882a915a1-HHS-rxl3-cd]; Epperson, Scott (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884f3347a42048deb11c01980beccbc2-HHS-gbq7-cd]; Andes, Linda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f7897f96c74f229c4795e534d64f17-HHS-fwf7-cd]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group



---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; rburke@cdc.gov;  
Walke, Henry (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5177bdc372504f2a81c595838af26e3b-HHS-hfw3-cd]; Yang, Quanhe (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=be02c99e79784b699c0ca9056efaf6d4-HHS-qay0-cd]; Dawood, Fatimah S (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=58641a45c9ed4bef84ba434e5a685af8-HHS-hgj0-cd];  
Emelia.Benjamin (b)(6) mjessup (b)(6) tavor (b)(6) jessica.lilley (b)(6)  
we (b)(6)

**Subject:** 2019-nCoV/COVID-19 treatment; Vaccine injury table; Epitope database evidence; Ebola vaccine will cause rice allergy epidemic

IgE mediated sensitization to peptides that have homology to 2019-nCoV/SARS-CoV-2 peptides may contribute to disease severity. In that case, antihistamines and other allergy treatments such as mast cell stabilizers may help reduce infection severity.

A BLASTP analysis of 2019-nCoV/SARS-CoV-2 proteome against common vaccine antigens was performed. Preliminary results suggest that IgE mediated sensitization to common vaccine antigens can result in cross reactive immune responses to 2019-nCoV/SARS-CoV-2.

Please see details of the mechanisms here:

Influenza vaccines and dengue-like disease

<https://www.bmj.com/content/360/bmj.k1378/rr-15>

<https://www.quora.com/Why-was-the-flu-so-deadly-in-outbreaks-in-the-past-And-what-made-the-flu-become-less-deadly/answers/86456279>

Interestingly, CNN reports that the Shanghai Institute of Materia Medica and the Wuhan Institute of Virology, discovered that Shuanghuanglian (SHL) - a traditional Chinese herbal remedy, could "inhibit" the 2019-nCoV/SARS-CoV-2 infection.

<https://www.cnn.com/2020/02/01/asia/chinese-traditional-medicine-claims-coronavirus-intl-scli-hnk/index.html>

*Shuang-Huang-Lian Attenuates Airway Hyperresponsiveness and Inflammation in a Shrimp Protein-Induced Murine Asthma Model.*

<https://www.ncbi.nlm.nih.gov/pubmed/30713573>

SHL as described in the article above, can act as a mast cell stabilizer. So it is understandable that SHL can help in 2019-nCoV/SARS-CoV-2 infection for reasons I detailed above.

Increasing indoor temperature may be a relatively easy way to reduce transmission and reduce disease severity of 2019-nCoV/SARS-CoV-2 infection.

Of course this is in general a good idea even for influenza/common cold virus transmission.

---

Updated:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditions

Latest version with hyperlinks, will open in your PDF application:

[https://zenodo.org/record/3647593/files/vbitr2\\_final.pdf?download=1](https://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1)

All versions: <https://doi.org/10.5281/zenodo.2582634>

---

"Scientists" at the global vaccine safety summit spill the beans: There is no science behind vaccine safety claims, it's a fairy tale.

The party is over folks.

<https://youtu.be/s2IujhTdCLE>

---

ERVEBO Ebola vaccine will create a rice allergy epidemic, add to numerous autoimmune diseases, cancer and make Ebola disease even more severe. Design for safety and vaccine safety regulation remain abject failures. Incompetence or indifference?

<https://doi.org/10.5281/zenodo.3595020>

---

Analyzing 23000+ epitopes covering 82 autoimmune diseases in the Immune Epitope Database, 57% have only one and 78% have up to two amino acid residue differences compared to animal, fungal or plant peptides present in vaccines; an unmistakable signature of the role of vaccines in their etiologies

<https://doi.org/10.5281/zenodo.3603480>

---

**Analyzing 23000+ epitopes covering 82 autoimmune diseases in the Immune Epitope Database, 57% have only one and 78% have up to two amino acid residue differences compared to animal, fungal or plant peptides present in vaccines; an unmistakable signature of the role of vaccines in their etiologies**

Vinu Arumugham

Jan 2020

(b)(6)

### Lay summary

Proteins are a chain of amino acids. Proteins can have up to several hundred amino acids. Snippets of proteins (peptides), 7-15 amino acids in length are important in immunology. There are 20 types of amino acids. Each is assigned a letter (1 letter code).

Antibodies are proteins that can bind to peptides that have a specific amino acid sequence. Such a target peptide is known as an epitope. When an antibody binds to a peptide (which is part of a protein, which in turn may be part of a cell surface), it can trigger an immune attack on the cell. If the cell were a bacterium, the bacterium would be killed.

Humans (like all organisms) are made of numerous proteins (self proteins). So we have self-proteins, self-peptides and self-epitopes. In a healthy person, the body will not make antibodies that bind strongly to self-peptides (self-tolerance).

DNA is a chain of base-pairs. The DNA base-pair sequence determines the amino acid sequence in the protein produced. If there is a mutation that alters a single base-pair, the resulting protein will have a single amino acid that is altered. To prevent cancer, the immune system is capable of making antibodies against such altered peptides. Such antibodies can also weakly bind (cross react) to the unaltered normal peptide thus resulting in destruction of some healthy cells.

Say a normal protein has the following peptide (10 amino acids, each represented by its 1 letter code):

ALSTLVVNKI

Say DNA in a cell mutates due to a carcinogen exposure and it alters the protein thus resulting in this peptide with a single amino acid change:

ALSTLVVSKI

When the immune system makes antibodies targeted at ALSTLVVSKI (to attack the cell with the DNA mutation), the same antibodies can weakly bind to the normal ALSTLVVNKI peptide.

ALSTLVVNKI is an epitope associated with rheumatoid arthritis (RA).

So as a result of the immune system defending against cancer, the person can develop RA.

Now consider vaccines containing animal proteins. Animal proteins are very similar to human proteins, containing only occasional amino acid differences. An animal peptide could therefore have the ALSTLVVSKI sequence. Such a vaccine would fool the immune system into creating an anti-cancer immune response, creating antibodies targeted at ALSTLVVSKI. The result is vaccine induced RA.

Therefore one can predict that analyzing epitopes associated with autoimmune diseases, such single amino acid difference compared to animal peptides present in vaccines, would occur more frequently than can be expected merely by chance. The analysis confirms that this prediction is valid.

### **Abstract**

The National Institute of Allergy and Infectious Diseases (NIAID) sponsors the Immune Epitope Data Base (IEDB). IEDB contains epitopes identified from the medical literature and organized by diseases and categories of diseases. All epitopes (23000+) associated with 82 autoimmune diseases in humans were analyzed.

The role of animal, plant, fungal proteins contained in vaccines in the etiology of autoimmune diseases have been described in humans and animals. BLASTP was used to analyze IEDB derived epitopes for sequence alignment to animal, plant, fungal (APF) proteins present in vaccines and biologics. Specifically, the search was performed against bovine, chicken, porcine, guinea pig, African green monkey, Chinese hamster, murine, peanut, soy, wheat, corn, sesame and *Saccharomyces cerevisiae* proteomes.

The results show that 57% of epitopes differed by exactly one amino acid residue from an APF peptide. 78% of the epitopes differed by up to two amino acid residues from an APF peptide. The rest of the epitopes were either identical or differed by more than two amino acid residues.

A majority of IEDB epitopes analyzed were 9-mer peptides. Comparing randomly selected 9-mer human peptides with APF proteomes, the probability of single amino acid residue difference (SAARD) outcomes was derived. This was used to estimate the probability that actual IEDB SAARD alignments to APF peptides were merely a chance outcome. The estimates show that the probability that the observed IEDB alignments to APF

being merely a chance outcome are vanishingly small. So the results make it absolutely clear that APF proteins in vaccines cause all these autoimmune diseases.

## **Introduction**

Vaccines contain thousands of residual animal, plant and fungal (APF) proteins from the manufacturing process (1–6). 293 chicken proteins were identified in the influenza vaccine (7), for example. Actin and vimentin proteins were detected in the Priorix Tetra vaccine (8). Immunization with homologous xenogeneic antigens resulting in autoimmune diseases has been known for at least 40 years (9). Vaccines that contain bovine proteins caused autoimmunity in dogs (10). We previously described the immunological mechanism involved in autoimmunity induction by immunization with homologous xenogeneic antigens (11).

Cancer cells have minor differences when compared to healthy cells. Due to mutation of the DNA encoding the proteins, cancer cells can display altered proteins on their surface. Healthy cancer defense mechanisms include immune responses directed at such altered proteins. Therefore an immune response directed against cancer cells always carries a risk of cross reactive immune responses against healthy cells displaying the unaltered protein. Therefore, cancer induced autoimmune responses are a consequence of normal, healthy immune system behavior.

Animal proteins have minor differences compared to human proteins. Peptides that are identical between humans and animals are unlikely to cause any problem due to strong self tolerance. However, peptides with one amino acid residue difference produce the strongest cross reactive immune responses (11). They are ideally suited to induce autoimmune diseases. Injecting animal proteins results in anti-cancer immune responses because the immune system perceives animal proteins as altered human proteins. Adjuvants in the vaccine boost this anti-cancer immune response. This artificial anti-cancer response directed at thousands of APF proteins in vaccines or biologics, therefore cross react and cause numerous autoimmune disorders.

For this reason, one can predict that single amino acid residue difference (SAARD) between autoimmune disease related epitopes in the IEDB and homologous APF peptides in vaccines, would occur at a higher probability than by mere chance. We perform a BLASTP analysis to verify.

## **Methods**

Basic local alignment search tool for proteins (BLASTP) (12), Universal Protein Resource (UniProt)(13) and the Immune Epitope Database (IEDB) (14) were used for bioinformatics analysis.

Specifically, the BLASTP sequence alignment of IEDB peptides was performed against bovine, chick, porcine, guinea pig, African green monkey, Chinese hamster, murine, peanut, soy, wheat, corn, sesame and *Saccharomyces cerevisiae* proteomes. Vaccines and biologics contain residual proteins from all these organism due to media used to grow viruses or bacteria, recombinant cells/organisms used for protein expression or as excipients.

## **Results**

57% of IEDB peptides have a SAARD and 78% have up to two amino acid differences compared to animal, fungal or plant peptides present in vaccines.

## **Discussion**

Could this result be a chance occurrence?

A majority of IEDB epitopes analyzed were 9-mer peptides. Five thousand 9-mer peptides were chosen at random from the human proteome. BLASTP was run using these peptides to compare against each organism's

proteome or a subset. This provides us the probability that randomly selected human peptides have an alignment providing a SAARD compared to peptides from these organisms. These are listed in table 1 under “ Random SAARD alignment”. Given this, we can compute the probability of the actual SAARD alignment to IEDB epitopes, occurring by chance. This is listed in table 1 under “Estimated probability of actual SAARD outcome occurring just by chance”.

For a simple coin toss example, we would perform the calculation as follows:

Computing probability of say a 7 heads, 3 tails outcome of 10 trials of a fair coin:

$$\text{Probability} = (0.5^7) \times (0.5^3) \times 10! / (7! \times 3!)$$

Where:

0.5 is the probability of a head or tail outcome of a fair coin.

For an unfair coin, say probability of head outcome = 0.4 and tail outcome 0.6, we would have:

$$\text{Probability} = (0.4^7) \times (0.6^3) \times 10! / (7! \times 3!)$$

For the IEDB peptide probability analysis, the outcome is for 23192 trials (peptides).

The “head outcome” is the “Random SAARD alignment ” entries in table 1. The “tail outcome” probability is 1-”head outcome”.

Sample calculation for Chinese Hamster:

$$\text{Probability} = ((889/5000)^{4574}) \times ((4111/5000)^{18618}) \times 23192! / (4574! \times 18618!)$$

$$\text{Probability} = 1.488\text{e-}15$$

Where: 889\*100/5000 = 17.8% is the entry in Table 1 for Chinese Hamster. BLASTP analysis shows 889 SAARD out of 5000 peptides analyzed.

And, 4574\*100/23192=19.7% is the IEDB entry in Table 1 for Chinese Hamster. BLASTP analysis shows 4574 SAARD out of 23192 peptides analyzed.

So the 1.488e-15 value is the probability that we will have exactly 4574 SAARD alignments out of 23192 peptides. The probability goes down for all values > 4574. Conservatively, applying the same probability as for 4574, to all values >4574, we can calculate the probability of the chance occurrence of 4574 or greater number of SAARD alignments as 1.488e15 \* 18618 = 27e-12, entry in table.

The Gnome calculator was used to perform these calculations and the results were verified using the Qalculate! calculator and WolframAlpha (15) since spreadsheets are unable to perform these calculations.

**Table 1**

Organism	Random SAARD alignment Number of Peptides(%)	Actual (IEDB) SAARD alignment Number of Peptides (%)	Estimated probability of actual SAARD outcome occurring just by chance	Remarks
African green monkey ( <i>Chlorocebus aethiops</i> )	26 (0.5)	420 (1.8)	~1.7e-96	Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases.
Cow ( <i>Bos taurus</i> )	936 (18.7)	4385 (18.9)	~1	There are two possibilities. (1) This outcome occurred just by chance. (2) The

Organism	Random SAARD alignment Number of Peptides(%)	Actual (IEDB) SAARD alignment Number of Peptides (%)	Estimated probability of actual SAARD outcome occurring just by chance	Remarks
				assumption that all cow proteins are present in the vaccines in equal amount is not true. We know that cow's milk, bovine gelatin, bovine serum albumin are used in vaccines. So these proteins and proteins present in tissues in the vicinity, are included in vaccines but other cow proteins may not be present. This is the more likely explanation. Please see Cow's milk entry below.
Cow's Milk ( <i>Bos taurus</i> )	0 (0)	12 (0.05)	0	Probability of this outcome occurring just by chance is 0. So these animal proteins in vaccines, caused these diseases.
Chinese Hamster ( <i>Cricetulus griseus</i> )	889 (17.8)	4574 (19.7)	~27e-12	Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, biologics caused these diseases.
Chicken ( <i>Gallus gallus</i> )	536 (10.7)	3901 (16.8)	<1e-100	Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases. Unlike bovine, porcine and murine proteins, since chicken egg or embryo is used for vaccine manufacture, all chicken proteins can be present in vaccines.
Guinea Pig ( <i>Cavia porcellus</i> )	837 (16.7)	4439 (19.1)	~1e-18	Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases.
Mice ( <i>Mus musculus</i> )	940 (18.8)	4467 (19.3)	~1	There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all mice proteins are present in biologics in equal amount is not true. We know that mice myeloma cells are used in biologics. So these proteins and proteins present in tissues in the vicinity, are present in biologics but other mice proteins may not be present. This is the more likely explanation.
Maize ( <i>Zea mays</i> )	303 (6.1)	1667 (7.2)	~5e-9	Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these

Organism	Random SAARD alignment Number of Peptides(%)	Actual (IEDB) SAARD alignment Number of Peptides (%)	Estimated probability of actual SAARD outcome occurring just by chance	Remarks
				diseases.
Peanut ( <i>Arachis hypogaea</i> )	223 (4.5)	1697 (7.3)	~79e-81	Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.
Yeast ( <i>Saccharomyces cerevisiae</i> )	64 (1.3)	828 (3.6)	<1e-100	Probability of this outcome occurring just by chance is vanishingly small. So these fungal proteins in vaccines, biologics caused these diseases.
Sesame ( <i>Sesamum indicum</i> )	155 (3.1)	1398 (6.0)	<1e-100	Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.
Soy ( <i>Glycine max</i> )	215 (4.3)	1548 (6.7)	~86e-59	Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.
Pig ( <i>Sus scrofa</i> )	963 (19.3)	4407 (19.0)	~1	There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all porcine proteins are present in the vaccines in equal amount is not true. We know that porcine gelatin is used in vaccines. So these proteins and proteins present in tissues in the vicinity are included in vaccines but other porcine proteins may not be present. This is the more likely explanation.
Wheat ( <i>Triticum aestivum</i> )	138 (2.8)	977 (4.2)	~18e-33	Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.

The calculations make it clear that the findings cannot be merely a chance outcome and that immunization against animal/plant/fungal antigens in the vaccines do cause these autoimmune diseases in the IEDB.

### Conclusion

Vaccines containing animal, plant or fungal proteins are extremely dangerous and cause numerous autoimmune diseases and cancer (16–19). All non-target proteins in vaccines must be immediately removed using processes such as affinity chromatography (20).

## References

1. Kattan JD, Cox AL, Nowak-Wegrzyn A, Gimenez G, Bardina L, Sampson HA, et al. Allergic reactions to diphtheria, tetanus, and acellular pertussis vaccines among children with milk allergy. *J Allergy Clin Immunol*. 2011;Conference(var.pagings):AB238.
2. Arumugham V. Oxford Vaccine Group Vaccine Knowledge Project's Vaccine Ingredient and vaccine safety misinformation exposed [Internet]. 2019 [cited 2019 Dec 11]. Available from: <https://doi.org/10.5281/zenodo.3477854>
3. National Academies of Sciences and Medicine E. Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy. Stallings VA, Oria MP, editors. Washington, DC: The National Academies Press; 2017.
4. Gardasil Package Insert [Internet]. Available from: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf>
5. ENGERIX-B HIGHLIGHTS OF PRESCRIBING INFORMATION [Internet]. Available from: <https://www.fda.gov/media/79341/download>
6. Arumugham V, Trushin M V. Role of NMDA receptor autoimmunity induced by food protein containing vaccines, in the etiology of autism, type 1 diabetes, neuropsychiatric and neurodegenerative disorders [Internet]. *International Journal of Pharmaceutical Research*. 2019 [cited 2019 Apr 15]. p. 428–37. Available from: <https://doi.org/10.5281/zenodo.1463600>
7. Jacob L, Leib R, Ollila HM, Bonvalet M, Adams CM, Mignot E. Comparison of Pandemrix and Arepanrix, two pH1N1 AS03-adjuvanted vaccines differentially associated with narcolepsy development. *Brain Behav Immun*. 2015 Jul;47:44–57.
8. Corvelva. Vaccinegate: Study on the chemical composition profile of Priorix Tetra [Internet]. 2018 [cited 2019 Aug 24]. Available from: <https://drive.google.com/file/d/1cNtdBczAX1-xowPEDep1kZOjy84IypAB/view>
9. Arumugham V. Vaccination with bovine, chick, yeast antigens synthesizes cross-reactive antibodies targeting human acetylcholine receptor and MuSK protein to cause Myasthenia Gravis: Confirmed by natural experiment (VAERS data), bioinformatics, case reports, animal experiments and titer study [Internet]. 2019 [cited 2019 Sep 16]. Available from: <https://doi.org/10.5281/zenodo.3421558>
10. Hogenesch H, Azcona-Olivera J, Scott-Moncrieff C, Snyder PW, Glickman LT. Vaccine-induced autoimmunity in the dog. *Adv Vet Med*. 1999;41:733–47.
11. Arumugham V, Trushin M V. Cancer immunology, bioinformatics and chemokine evidence link vaccines contaminated with animal proteins to autoimmune disease: a detailed look at Crohn's disease and Vitiligo. *J Pharm Sci Res*. 2018;10(8):2106.
12. Altschul SF, Madden TL, Schäffer AA, Zhang J, Zhang Z, Miller W, et al. Gapped BLAST and PSI-BLAST: a new generation of protein database search programs. *Nucleic Acids Res*. 1997;25(17):3389–402.
13. UniProt: the universal protein knowledgebase. *Nucleic Acids Res*. 2017 Jan 4;45(D1):D158–69.



14. Vita R, Mahajan S, Overton JA, Dhanda SK, Martini S, Cantrell JR, et al. The Immune Epitope Database (IEDB): 2018 update. *Nucleic Acids Res. Oxford University Press*; 2019;47(D1):D339–43.
15. Wolfram|Alpha: Computational Intelligence [Internet]. [cited 2020 Jan 8]. Available from: <https://www.wolframalpha.com/>
16. Arumugham V. Vaccines and Biologics injury table based on mechanistic evidence – Mar 2019 [Internet]. 2019 [cited 2019 May 16]. Available from: <https://zenodo.org/record/2582635/files/viittoc0302http.pdf?download=1>
17. Arumugham V. As predicted, animal protein containing biologics induce de novo autoimmune disorders [Internet]. 2019 [cited 2019 Dec 29]. Available from: <https://doi.org/10.5281/zenodo.3483322>
18. Arumugham V. Expanding ASIA to GAVIDOTTIR : GAmut of Vaccine Induced Damage emphasizing Off Target Immune Responses [Internet]. 2019 [cited 2019 Oct 23]. Available from: <https://doi.org/10.5281/zenodo.3478840>
19. Arumugham V. Role of anti-carbonic anhydrase 2 antibodies induced by vaccine antigens, in the etiology of acute myeloid leukemia and other malignancies [Internet]. 2019 [cited 2019 Nov 14]. Available from: <https://doi.org/10.5281/zenodo.3534442>
20. Zhao M, Vandersluis M, Stout J, Haupts U, Sanders M, Jacquemart R. Affinity chromatography for vaccines manufacturing: Finally ready for prime time? *Vaccine. Netherlands*; 2018 Apr;

---

**From:** Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109E347D6AC4]  
**Sent:** 2/29/2020 6:55:02 AM  
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus  
**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,, (b)(6)  
**Start:** 3/2/2020 1:15:00 PM  
**End:** 3/2/2020 2:20:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Amin, Stacy; McWilliams, Carly; Janik, Heather; Caliguiri, Laura; McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F; Kumar, Dinesh; Beers, Donald

Your meeting was found to be out of date and has been automatically updated.

---

Sent by Microsoft Exchange Server

---

**From:** Harrison, Brian (HHS/IOS) [Brian.Harrison@hhs.gov]  
**Sent:** 2/29/2020 6:57:35 AM  
**To:** AMA2 (OS/IOS) [AMA2@HHS.GOV]  
**CC:** Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]  
**Subject:** 465ACC69-325D-42B7-841D-B1CA1F421ADF.docx  
**Attachments:** 465ACC69-325D-42B7-841D-B1CA1F421ADF.docx; ATT00001.htm

---

**From:** Harrison, Brian (HHS/IOS) [Brian.Harrison@hhs.gov]  
**Sent:** 2/29/2020 6:59:04 AM  
**To:** AMA2 (OS/IOS) [AMA2@HHS.GOV]  
**CC:** Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]  
**Subject:** Fwd: Diagnostics  
**Attachments:** IIE nCoV guidance\_Passback 2-28-20 1030pm\_CLEAN.docx; ATT00001.htm

**From:** "Mango, Paul (HHS/IOS)" <Paul.Mango@hhs.gov>  
**Date:** February 29, 2020 at 6:48:14 AM EST  
**To:** "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>  
**Subject:** Fwd: Diagnostics

(b)(5)

FDA

team did a very nice job as did Ann's team

Sent from my iPhone

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/29/2020 7:38:13 AM  
**To:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**Subject:** Re: COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants + Materials + Seating Chart

Thanks, Janice

Sent from my iPad

On Feb 29, 2020, at 7:24 AM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

Good morning!

Updated invite and background material just came in this morning for the 10:00 am.

Thanks!

-j

-----Original Appointment-----

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** Friday, February 28, 2020 5:30 PM  
**To:** Short, Marc T. EOP/OVP; Shellooe, Ryan P. EOP/NSC; Ferro, Phil J. EOP/NSC; Hurst, Natalie R. EOP/OVP; AMA2@HHS.GOV; as2ktc (b)(6) BiegunSE (b)(6) Bigley, Mark C. EOP/OMB; Devin.O'Malley@treasury.gov; WILLIAM.FERRARA (b)(6) Grisham, Stephanie A. EOP/WHO; Blair, Robert B. EOP/WHO; Harrison, Brian (OS); Miller, Katie R. EOP/OVP; Hodgson, Christopher M. EOP/OVP; Amie Kalsbeek (DOT); Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; Cetron, Martin (CDC); Chafin, Kelly B. EOP/NSC; Conant, Ann M. EOP/OMB; Conley, Sean P. CDR USN WHMO/WHMU; Conrad, Patricia L (NIH); Davis, May M. EOP/WHO; Ditto, Jessica E. EOP/WHO; DL Chief of Staff Office; donna.oberry@dot.gov; Duffey, Michael P. EOP/OMB; Eisenberg, John A. EOP/WHO; Fabina, Lauren C. EOP/NSC; Fauci, Anthony S (NIH); Grogan, Joseph J. EOP/WHO; Hemme, Jake W. EOP/NSC; Hennessey, Millicent S. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Jacqueline.Colli@va.gov; Kan, Derek T. EOP/OMB; Kenneth.p.rapuano.civ (b)(6) Liddell, Christopher P. EOP/WHO; Miller, Julie L. EOP/OMB; Mulvaney, Mick M. EOP/WHO; Nesheiwat, Julia EOP/NSC; Robert.g.salesses.civ (b)(6) Pataki, Tim A. EOP/WHO; Pottinger, Matthew F. EOP/WHO; Riggs, Charlotte R. EOP/WHO; Redfield, Robert R (CDC); Kadlec, Robert P (OS); Ruggiero, Anthony J. EOP/NSC; Scher, Adam A. EOP/OMB; Sinclair, Michael R. EOP/NSC; Joel.Szabat@dot.gov; Tignor, Beth (OS); Ulyyot, John L. EOP/NSC; Williams, Michael B. EOP/WHO; Wilson, John Mark M. EOP/NSC; Woolfolk, Jon J. EOP/OVP; Lin, Merry S. EOP/WHO; Zachary.McEntee@treasury.gov; Adams, Jerome (OS); DL OVP NSA EXECSEC; Bauer, Zachary C. EOP/OVP; Moore, Caroline E. EOP/WHO; Galkowski, James J. EOP/WHO; OVPSchedule; Droegemeier, Kelvin K. EOP/OSTP; Baum, Kristina R. EOP/OSTP; Troye, Olivia EOP/NSC; Loyetcj (b)(6) HattinghE (b)(6) NanavattyKB (b)(6) Sheehy, Janice; Cavanaugh, Brian J. EOP/NSC  
**Cc:** Thurston, Eliza C. EOP/OVP; Scully, Bethany S. EOP/OVP; Stickles, Brendan R. EOP/OVP; Hahn, Stephen; McBride, Emily J. EOP/WHO; Schuchat, Anne (CDC); Paz, Brooke L. EOP/WHO  
**Subject:** COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants + Materials + Seating Chart  
**When:** Saturday, February 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** WHSR JFK

All,

There will be a **Coronavirus Task Force Principal's Meeting** at **10:00am** in the **White House Situation Room**.  
Agenda and read-ahead materials attached.

**Please see attached seating chart for approved attendees.**

Thank you,

**Natalie Hurst**

Executive Assistant to the Chief of Staff

~~The Office of the~~ Vice President

**(b)(6)**

<UPDATED - Supply Chain Options - N95 (PPE).docx>

<VPOTUS COVID19 - Seating Chart.pdf>

<Travel Restrictions Grid.jpg>

<Task Force Agenda 2.29.2020 1000 (005).docx>

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/29/2020 7:46:57 AM  
**To:** Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]  
**Subject:** Wording

(b)(5)

Sent from my iPad

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/29/2020 8:10:51 AM  
**To:** Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]  
**Subject:** Fwd: NYS Wadsworth

Sent from my iPhone

Begin forwarded message:

**From:** "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>  
**Date:** February 29, 2020 at 7:53:29 AM EST  
**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Cc:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: NYS Wadsworth

Yes, will do. We asked them this morning to also include IDT and Biosearch.

I do have another ask though. IDT made test kits for CDC/public health labs and for distribution to other labs. (b)(5)

(b)(5)

**(b)(5)**

We just an email from Dr. Redfield or Dan to say that the (b)(5)  
(b)(5) to Wadsworth Center, IDT, and Biosearch.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Saturday, February 29, 2020 7:50 AM  
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: NYS Wadsworth

Spoke to Redfield and asked him to send the language. It would be great to tell the VP this AM. Would you keep me updated?  
Thanks

Sent from my iPad

On Feb 28, 2020, at 10:10 PM, Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)> wrote:



Wadsworth sent us their EUA this afternoon. They were missing one important test which they are performing. We don't have a firm timeframe on when we will receive it but we do not anticipate we will be granting the EUA tomorrow

In addition, Wadsworth didn't perform validation testing as you otherwise would. Instead they conducted a bridging study to compare performance with the modified N1/N2 CDC test. That testing is premised on their ability to reference the CDC's data. We've asked if they would give a right of reference to Wadsworth as this is important not just for Wadsworth but some other test developers, as well. We asked that, if CDC agrees, they just email us that "The New York State Wadsworth Center can reference the data in the CDC 2019 nCoV EUA application".

We'll follow up but if we do not hear back from them tomorrow morning I may ask you to reach out to Redfield. This should be a no-brainer.

**From:** Natalie.R.Hurst@ovp.eop.gov (b)(6)  
**Sent:** 2/29/2020 9:31:38 AM  
**To:** Short, Marc T. EOP/OVP (b)(6); Shellooe, Ryan P. EOP/NSC; Ferro, Phil J. EOP/NSC; Hurst, Natalie R. EOP/OVP; AMA2@HHS.GOV; Stufft, Julie M. EOP/NSC; as2ktd (b)(6); BiegunSE (b)(6); Risch, Carl C; Jennifer.L.Naaden@hud.gov; Bigley, Mark C. EOP/OMB; Devin.O'Malley@treasury.gov; William Ferrara (CBP); Grisham, Stephanie A. EOP/WHO; Blair, Robert B. EOP/WHO; Harrison, Brian (OS); Miller, Katie R. EOP/OVP; Hodgson, Christopher M. EOP/OVP; Amie Kalsbeek (DOT); Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; Cetron, Martin (CDC); Chafin, Kelly B. EOP/NSC; Conant, Ann M. EOP/OMB; Conley, Sean P. CDR USN WHMO/WHMU; Conrad, Patricia L (NIH); Davis, May M. EOP/WHO; Ditto, Jessica E. EOP/WHO; DL Chief of Staff Office; donna.oberry@dot.gov; Duffey, Michael P. EOP/OMB; Eisenberg, John A. EOP/WHO; Fabina, Lauren C. EOP/NSC; Fauci, Anthony S (NIH); Grogan, Joseph J. EOP/WHO; Hemme, Jake W. EOP/NSC; Hennessey, Millicent S. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Jacqueline.Colli@va.gov; Kan, Derek T. EOP/OMB; Kenneth.p.rapuano.civ (b)(6); Liddell, Christopher P. EOP/WHO; Miller, Julie L. EOP/OMB; Mulvaney, Mick M. EOP/WHO; Nesheiwat, Julia EOP/NSC; Robert.g.saleses.civ@mail.mil; Pataki, Tim A. EOP/WHO; Pottinger, Matthew F. EOP/WHO; Riggs, Charlotte R. EOP/WHO; Redfield, Robert R (CDC); Kadlec, Robert P (OS); Ruggiero, Anthony J. EOP/NSC; Scher, Adam A. EOP/OMB; Sinclair, Michael R. EOP/NSC; Joel.Szabat@dot.gov; Tignor, Beth (OS); Ulliyot, John L. EOP/NSC; Williams, Michael B. EOP/WHO; Wilson, John Mark M. EOP/NSC; Woolfolk, Jon J. EOP/OVP; Lin, Merry S. EOP/WHO; Zachary.McEntee@treasury.gov; Adams, Jerome (OS); DL OVP NSA EXECSEC; Bauer, Zachary C. EOP/OVP; Moore, Caroline E. EOP/WHO; Galkowski, James J. EOP/WHO; OVPSchedule; Droegemeier, Kelvin K. EOP/OSTP; Baum, Kristina R. EOP/OSTP; Troye, Olivia EOP/NSC; Loyetj (b)(6); HattinghEF (b)(6); NanavattyK (b)(6); Sheehy, Janice; Cavanaugh, Brian J. EOP/NSC; Thurston, Eliza C. EOP/OVP; Scully, Bethany S. EOP/OVP; Stickles, Brendan R. EOP/OVP; Hahn, Stephen; McBride, Emily J. EOP/WHO; Schuchat, Anne (CDC); Paz, Brooke L. EOP/WHO

**Subject:** COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants + Materials + Updated Seating Chart  
**Attachments:** UPDATED - Supply Chain Options - N95 (PPE).docx; Task Force Agenda 2.29.2020 1000 (005).docx; 02.29.2020 TAB C Travel Restrictions Options Grid.jpg; Seating Chart.PNG  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Busy

All,

There will be a **Coronavirus Task Force Principal's Meeting** at **10:00am** in the **White House Situation Room**. Agenda and read-ahead materials attached.

**Please see attached updated seating chart for approved attendees. All other participants will be directed to an overflow room.**

Thank you,

**Natalie Hurst**  
Executive Assistant to the Chief of Staff  
The Office of the Vice President

(b)(6)

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/29/2020 9:51:46 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**CC:** Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]

**Subject:** Oregon announces first, presumptive case of novel coronavirus

<https://www.oregon.gov/oha/ERD/Pages/Oregon-First-Presumptive-Case-Novel-Coronavirus.aspx>

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/29/2020 9:53:33 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]  
**Subject:** CDC Announces Additional COVID-19 Presumptive Positive Cases

<https://www.cdc.gov/media/releases/2020/s0228-additional-COVID-19-cases.html>

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 2/29/2020 10:24:02 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Fwd: Diagnostic guidance\_PR final 10am.docx  
**Attachments:** Diagnostic guidance\_PR final 10am.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

**From:** "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>  
**Date:** February 29, 2020 at 9:57:25 AM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Diagnostic guidance\_PR final 10am.docx

Final proofed copy

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 11:23:04 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angeliq ue A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo o, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caligui ri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccomo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; Clarke, Mary Beth  
**Subject:** COVID-19 Agency Executive Group meeting  
**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)  
**Start:** 3/1/2020 3:00:00 PM  
**End:** 3/1/2020 3:15:00 PM  
**Show Time As:** Tentative

**Recurrence:** Weekly  
every Sunday from 3:00 PM to 3:15 PM  
**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angeliq ue A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo o, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caligui ri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccomo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; Clarke, Mary Beth

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide high-level updates on key issues and activities on their respective areas as applicable.

**AEG DAILY CHECKLIST**

(b)(5)



**(b)(5)**

---

**From:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Sent:** 2/29/2020 11:23:07 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[Heather.Janik@fda.hhs.gov]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Clarke, Mary Beth  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Zeller, Mitchell  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Yiannas, Frank  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]  
CC: Stearn, Douglas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]

**Subject:** Canceled: COVID-19 Agency Executive Group meeting

**Attachments:** Untitled Attachment; Untitled Attachment

**Location:** CALL-IN ONLY: 1-877-465-7975, code:

**Start:** 3/1/2020 3:00:00 PM

**End:** 3/1/2020 3:15:00 PM

**Show Time As:** Free

---

**Importance:** High

**Recurrence:** Weekly  
every Sunday from 3:00 PM to 3:15 PM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccamo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; Clarke, Mary Beth; Zeller, Mitchell; Yiannas, Frank

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide high-level updates on key issues and activities on their respective areas as applicable.

**AEG DAILY CHECKLIST**

(b)(5)

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 11:23:07 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Clarke, Mary Beth  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]

**Subject:** COVID-19 Agency Executive Group meeting  
**Attachments:** Untitled Attachment  
**Location:** CALL-IN ONLY: 1-877-465-7975, code (b)(6)

**Start:** 3/1/2020 3:00:00 PM  
**End:** 3/1/2020 3:15:00 PM  
**Show Time As:** Busy

**Recurrence:** Weekly  
Occurs every Sunday from 3:00 PM to 3:15 PM effective 3/1/2020 until 8/16/2020.

---

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Janik, Heather; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccamo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; Clarke, Mary Beth

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide high-level updates on key issues and activities on their respective areas as applicable.

**AEG DAILY CHECKLIST**

**(b)(5)**

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/29/2020 4:00:09 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** Re: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Approved

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Date:** February 29, 2020 at 11:43:41 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** FOR YOUR REVIEW: tweets for today's action (EUA policy)

Dr. Hahn, here are the ones related to today's action. Yours are first 4 threads for @Steve. Thank you.

**EUA Press Release Tweets**  
**@Steve FDA Account**

**Thread 1**

1. Today, as part of our continuous approach to addressing #COVID19, FDA issued a policy regarding certain laboratories using tests they develop & validate for #coronavirus faster in order to achieve more rapid testing capacity in the U.S. Learn more: <https://go.usa.gov/xddFR>
2. Effective immediately, FDA does not intend to object to the use of these diagnostic tests to detect #COVID19 while such laboratories are pursuing an EUA with FDA.
3. We believe this policy strikes the right balance during this public health emergency. We will continue to help to ensure sound science prior to clinical testing and follow-up with the critical independent review from FDA, while quickly expanding testing capabilities in the U.S.
4. We are not changing our standards for issuing EUAs. Today's action reflects our public health commitment to addressing critical public health needs and rapidly responding and adapting to this dynamic & evolving situation.

(b)(5)



**(b)(5)**

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/29/2020 4:00:26 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** Re: FOR YOUR REVIEW: NY State EUA tweets

Approved

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Date:** February 29, 2020 at 11:41:48 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** FOR YOUR REVIEW: NY State EUA tweets

Dr. Hahn, please review tweets on NY State EUA to go once EUA is issued. Other tweets for today's action coming your way separately.

**NY STATE EUA TWEETS**

(b)(5)

2. Coordination across all levels of government & with public health partners domestically & abroad is one of the reasons we remain optimistic about our country's preparedness & readiness despite the seriousness of the #COVID19 outbreak.

(b)(5)

4. We recognize that increased testing capabilities are a crucial component to coordinated government efforts in response to the #coronavirus outbreak & continue to work with EUA developers to hasten the development & accessibility of critical medical products like diagnostics.

(b)(5)

**(b)(5)**

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/29/2020 4:07:03 PM  
**Subject:** Afternoon Edition of Dr. Levitt's COVID-19 Update on 29 February 2020  
**Attachments:** Bogoch, et. al. Est of Iranian COVID-19.pdf

Dear All,

Thank you for meeting with President Trump and VP Pence in the Situation Room this morning. Here are brief summaries of the articles I have read online or in journals today re: COVID-19/SARS-CoV-2:

**WH Press Briefing** this afternoon raised the level of risk for travel to Italy and South Korea and restricted travel from Iran to U.S. No airlights from China are allowed to land in U.S., as I understand the rules. See: <https://www.washingtonpost.com/world/2020/02/29/coronavirus-live-updates/>  
**I would ask the CDC to issue the official rulebook for travel to and from China, South Korea, Iran, and Italy ASAP.** The rules got lost in the Press Briefing as the reporters were more interested in blaming President Trump for everything. Even when the President gets it right, the press sees only: 'if it bleeds, it leads'. I was proud of President Trump at the Press Briefing.

My afternoon update yesterday questioned the number of COVID-19 cases in Iran based on a **BBC** report. Today another report in the **WSJ** also questioned the Iranian government's reported numbers. See: <https://www.wsj.com/articles/as-irans-leaders-contrast-coronavirus-doubts-emerge-over-national-tally-11582903223>

This **WSJ** article is based on a Bogoch, et. al. article *not peer reviewed on medRxiv*. See pdf above. This article bases its results on 3 exported cases of COVID-19 to Canada, Lebanon, and UAE. The WSJ statement that there are really 23,000 COVID-19 cases in Iran has a statistical range of 3770-53,470 in the Bogoch, et. al. paper. **The WSJ statement is incorrect.** The Bogoch, et. al. article may also be incorrect; I am not a statistician, but the Bogoch, et. al. article is a statistical exercise. **In my opinion, the CDC needs to determine the correct number of cases of COVID-19 in Iran. If there is a statistically significant number of COVID-19 cases, all countries should not allow Iranian aircraft to land at their airports.**

**American Journal of Roentgenology** has a recent article on the CXR and CT finding of COVID-19 c/w MERS and SARS findings. See pdf above. The **findings of these related coronaviruses are similar on CXR and CT**, but the authors found more bilaterality of opacities on CXR and CT with COVID-19. My thanks to Dr. Joseph Mansour for bringing this article to my attention.

Regarding the community acquired COVID-19 cases in California, Oregon, and Washington State, these states all have ports receiving shipments from Asia via freighters. **My opinion is that crews/officers of any freighter with a stop in Asia and docking in California, Oregon, or Washington State should remain on board their ship while in port.**

RGL, M.D.

Sent from Outlook

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/29/2020 5:09:41 PM  
**Subject:** Revised Afternoon Edition of Dr. Levitt's COVID-19 Update on 29 February 2020  
**Attachments:** Bogoch, et. al. Est of Iranian COVID-19.pdf; Coronavirus in comparison to MERS and SARS.pdf

All: All attachments now attached as well as my Disclaimer. RGL, M.D.

Sent from [Outlook](#)

---

**From:** Robert Levitt  
**Sent:** Saturday, February 29, 2020 3:07 PM  
**Subject:** Afternoon Edition of Dr. Levitt's COVID-19 Update on 29 February 2020

Dear All,

Thank you for meeting with President Trump and VP Pence in the Situation Room this morning. Here are brief summaries of the articles I have read online or in journals today re: COVID-19/SARS-CoV-2:

**WH Press Briefing** this afternoon raised the level of risk for travel to Italy and South Korea and restricted travel from Iran to U.S. No airlights from China are allowed to land in U.S., as I understand the rules. See: <https://www.washingtonpost.com/world/2020/02/29/coronavirus-live-updates/>  
**I would ask the CDC to issue the official rulebook for travel to and from China, South Korea, Iran, and Italy ASAP.** The rules got lost in the Press Briefing as the reporters were more interested in blaming President Trump for everything. Even when the President gets it right, the press sees only: 'if it bleeds, it leads'. I was proud of President Trump at the Press Briefing.

My afternoon update yesterday questioned the number of COVID-19 cases in Iran based on a **BBC** report. Today another report in the **WSJ** also questioned the Iranian government's reported numbers. See: <https://www.wsj.com/articles/as-irans-leaders-contract-coronavirus-doubts-emerge-over-national-tally-11582903223>

This **WSJ** article is based on a Bogoch, et. al. article *not peer reviewed on medRxiv*. See pdf above. This article bases its results on 3 exported cases of COVID-19 to Canada, Lebanon, and UAE. The WSJ statement that there are really 23,000 COVID-19 cases in Iran has a statistical range of 3770-53,470 in the Bogoch, et. al. paper. **The WSJ statement is incorrect.** The Bogoch, et. al. article may also be incorrect; I am not a statistician, but the Bogoch, et. al. article is a statistical exercise. **In my opinion, the CDC needs to determine the correct number of cases of COVID-19 in Iran. If there is a statistically significant number of COVID-19 cases, all countries should not allow Iranian aircraft to land at their airports.**

**American Journal of Roentgenology** has a recent article on the CXR and CT finding of COVID-19 c/w MERS and SARS findings. See pdf above. The **findings of these related coronaviruses are similar on CXR and CT**, but the authors found more bilaterality of opacities on CXR and CT with COVID-19. My thanks to Dr. Joseph Mansour for bringing this article to my attention.

Regarding the community acquired COVID-19 cases in California, Oregon, and Washington State, these states all have ports receiving shipments from Asia via freighters. **My opinion is that crews/officers of any freighter with a stop in Asia and docking in California, Oregon, or Washington State should remain on board their ship while in port.**

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

Sent from Outlook

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 8:37:29 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]

**Subject:** COVID-19 Agency Executive Group Meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting; Untitled Attachment  
**Location:** 1-877-465-7975, code (b)(6) in Conference Room (WO1/2102)  
**Start:** 3/2/2020 8:30:00 AM  
**End:** 3/2/2020 8:45:00 AM  
**Show Time As:** Tentative

---

**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, Thursday, and Friday from 8:30 AM to 8:45 AM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia; Rebello, Heidi

The meeting time has changed to provide updates in advance of TF calls. Thank you in advance for your cooperation in accommodating the schedule change. Note the location change to Bldg. 1, RM 2102 as well.

---

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

### **AEG DAILY CHECKLIST**

#### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

#### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

#### **Inspection Delays (ORA)**

#### **Travel Advisories (AIC)**

#### **UFA Deadlines At-Risk (ORA/Centers)**

#### **Personnel Considerations/Workforce Management (OO)**

#### **Other pressing issues**

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 8:37:29 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Rebello, Heidi  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
CC: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Clarke, Mary Beth  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; McWilliams, Carly  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]

**Subject:** COVID-19 Agency Executive Group Meeting

**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting

**Location:** 1-877-465-7975, code (b)(6) or Conference Room (WO1/2102)

**Start:** 3/2/2020 8:30:00 AM

**End:** 3/2/2020 8:45:00 AM

---

**Show Time As:** Tentative

**Recurrence:** Weekly

every Monday, Tuesday, Wednesday, Thursday, and Friday from 8:30 AM to 8:45 AM

**Required**

Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William;

**Attendees:**

Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia; Rebello, Heidi

The meeting time has changed to provide updates in advance of TF calls. Thank you in advance for your cooperation in accommodating the schedule change. Note the location change to Bldg. 1, RM 2102 as well.

---

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

### **AEG DAILY CHECKLIST**

#### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

#### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

#### **Inspection Delays (ORA)**

#### **Travel Advisories (AIC)**

#### **UFA Deadlines At-Risk (ORA/Centers)**

#### **Personnel Considerations/Workforce Management (OO)**

#### **Other pressing issues**

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 8:37:29 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdo, Mark [Mark.Abdo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Throckmorton, Douglas C [Douglas.Throckmorton@fda.hhs.gov]; Solberg, Tim [Tim.Solberg@fda.hhs.gov]; Keller, Melanie [Melanie.Keller@fda.hhs.gov]; Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Tyler, James [James.Tyler@fda.hhs.gov]; Beach, Carter [Carter.Beach@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]  
**CC:** Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Malais, Tanya [Tanya.Malais@fda.hhs.gov]; Janik, Heather [Heather.Janik@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Ricci, Linda J [Linda.Ricci@fda.hhs.gov]; O'Callaghan, Kathryn [Kathryn.OCallaghan@fda.hhs.gov]; Lynch, Sarah [Sarah.Lynch@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Bess, Demetrice [Demetrice.Bess@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Caccamo, Stephanie [Stephanie.Caccamo@fda.hhs.gov]; Ross, Bruce [Bruce.Ross@fda.hhs.gov]; Torres-Rivera, Sahra [Sahra.Torres-Rivera@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; Clarke, Mary Beth [marybeth.clarke@fda.hhs.gov]  
**Subject:** COVID-19 Agency Executive Group Meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: (b)(6) or Conference Room (WO1/2102)  
**Start:** 3/2/2020 8:30:00 AM  
**End:** 3/2/2020 8:45:00 AM  
**Show Time As:** Busy  
**Recurrence:** Weekly  
Occurs every weekday from 8:30 AM to 8:45 AM effective 3/2/2020 until 6/5/2020.  
**Required Attendees:** Hinton, Denise; Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia

The meeting time has changed to provide updates in advance of TF calls. Thank you in advance for your cooperation in accommodating the schedule change. Note the location change to Bldg. 1, RM 2102 as well.

---

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

#### **AEG DAILY CHECKLIST**

### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

### **Inspection Delays (ORA)**

### **Travel Advisories (AIC)**

### **UFA Deadlines At-Risk (ORA/Centers)**

### **Personnel Considerations/Workforce Management (OO)**

### **Other pressing issues**

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 8:37:29 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fecaf0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdoo, Mark [Mark.Abdoo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Throckmorton, Douglas C [Douglas.Throckmorton@fda.hhs.gov]; Solberg, Tim [Tim.Solberg@fda.hhs.gov]; Keller, Melanie [Melanie.Keller@fda.hhs.gov]; Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Tyler, James [James.Tyler@fda.hhs.gov]; Beach, Carter [Carter.Beach@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]  
**CC:** Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Malais, Tanya [Tanya.Malais@fda.hhs.gov]; Janik, Heather [Heather.Janik@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Ricci, Linda J [Linda.Ricci@fda.hhs.gov]; O'Callaghan, Kathryn [Kathryn.OCallaghan@fda.hhs.gov]; Lynch, Sarah [Sarah.Lynch@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Bess, Demetrice [Demetrice.Bess@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Caccamo, Stephanie [Stephanie.Caccamo@fda.hhs.gov]; Ross, Bruce [Bruce.Ross@fda.hhs.gov]; Torres-Rivera, Sahra [Sahra.Torres-Rivera@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]  
**Subject:** COVID-19 Agency Executive Group Meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting  
**Location:** 1-877-465-7975, code (b)(6) or Conference Room (WO1/2102)  
**Start:** 3/2/2020 8:30:00 AM  
**End:** 3/2/2020 8:45:00 AM  
**Show Time As:** Busy  
**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, Thursday, and Friday from 8:30 AM to 8:45 AM  
**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia

The meeting time has changed to provide updates in advance of TF calls. Thank you in advance for your cooperation in accommodating the schedule change. Note the location change to Bldg. 1, RM 2102 as well.

---

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.



AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

## **AEG DAILY CHECKLIST**

### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

### **Inspection Delays (ORA)**

### **Travel Advisories (AIC)**

### **UFA Deadlines At-Risk (ORA/Centers)**

### **Personnel Considerations/Workforce Management (OO)**

### **Other pressing issues**

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/29/2020 8:37:29 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
CC: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** COVID-19 Agency Executive Group Meeting

**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting

**Location:** 1-877-465-7975, code (b)(6) or Conference Room (WO1/2102)

**Start:** 3/2/2020 8:30:00 AM

**End:** 3/2/2020 8:45:00 AM

**Show Time As:** Tentative

**Recurrence:** Weekly

every Monday, Tuesday, Wednesday, Thursday, and Friday from 8:30 AM to 8:45 AM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William;

**Attendees:** Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caligui, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie;

The meeting time has changed to provide updates in advance of TF calls. Thank you in advance for your cooperation in accommodating the schedule change. Note the location change to Bldg. 1, RM 2102 as well.

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

## **AEG DAILY CHECKLIST**

### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

### **Inspection Delays (ORA)**

### **Travel Advisories (AIC)**

### **UFA Deadlines At-Risk (ORA/Centers)**

### **Personnel Considerations/Workforce Management (OO)**

### **Other pressing issues**

---

**From:** Redfield, Robert R. (CDC/OD) [olx1@cdc.gov]  
**Sent:** 2/29/2020 10:51:49 PM  
**To:** ama2@hhs.gov; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]  
**CC:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acsl-cd]  
**Subject:** Laboratory Diagnostic Test Timeline  
**Attachments:** CDC\_2019-nCoV lab timeline\_FINAL.docx

Dear Mr. Secretary-

Attached is the timeline you requested today from CDC and FDA.

Peace,

R3

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/1/2020 6:39:34 AM  
**To:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]  
**Subject:** as Testing Capacity in the U.S. (3).docx  
**Attachments:** as Testing Capacity in the U.S. (3).docx; ATT00001.txt

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/1/2020 6:44:48 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: COVID-19 Agency Executive Group Meeting  
**Location:** 1-877-465-7975, code: (b)(6) or Conference Room (WO1/2102)  
**Start:** 3/2/2020 8:30:00 AM  
**End:** 3/2/2020 8:45:00 AM  
  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/1/2020 6:44:59 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA Coronavirus update  
**Location:** CALL // 877-314-0346 (b)(6)  
**Start:** 3/1/2020 3:30:00 PM  
**End:** 3/1/2020 4:00:00 PM  
**Recurrence:** (none)



**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 3/1/2020 10:27:37 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**CC:** Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]

**Subject:** Update from Seattle King Co PH

<https://www.kingcounty.gov/depts/health/news/2020/February/29-covid19.aspx>

Public Health – Seattle & King County, Washington State Department of Health and the Centers for Disease Control and Prevention (CDC) are reporting three presumptive positive cases of novel coronavirus (COVID-19), including one person who died. This brings the total of presumptive positive cases in King County to four.

- Two of the confirmed cases are associated with LifeCare nursing facility in Kirkland, King County, Washington:
  - One is a health care worker from LifeCare. She is a woman in her 40s, is currently in satisfactory condition at Overlake Hospital, and she has no known travel outside the United States.

- The second case, a woman in her 70's, is a resident at LifeCare and is in serious condition at EvergreenHealth Hospital.
- In addition, over 50 individuals associated with LifeCare are reportedly ill with respiratory symptoms or hospitalized with pneumonia or other respiratory conditions of unknown cause and are being tested for COVID-19. Additional positive cases are expected.
- The death occurred in a patient at EvergreenHealth Hospital but was not a resident of the long-term care facility.

---

**From:** Robert Levitt (b)(6)  
**Sent:** 3/1/2020 11:29:42 AM  
**Subject:** Morning Edition Dr. Levitt's Update on COVID-19 for 1 March 2020/NYT Sunday Review has ACTION PLAN FOR TODAY

Dear All, Here are the articles I have read online this morning. The **WH Press Room Briefing** yesterday was an impetus to more ideas in press and online:

**Meet The Press** this morning had a panel of journalists and former WH press people. Consensus recommendation was to **make Dr. Fauci the face of the WH response to COVID-19**. He is a virologist with the knowledge and speech delivery to keep everyone at large calm and compliant with his instructions to the Nation. Today's episode not online yet; check later on the Internet.

**NPR** had an **interview with Laurie Garrett**, a science writer on epidemics. She wrote an article for **Foreign Policy** which lists her recommendations for avoiding COVID-19. Here is her article: <https://foreignpolicy.com/2020/01/25/wuhan-coronavirus-safety-china/>  
Her 10 recommendations are all valid, but following all 10 takes a lot of effort. **Her tenth recommendation on how to care for infected patient at home are spot-on**. It may come to the time where we should all wear gloves if out in public gatherings or at work or school. How many of these recommendations should be instituted today I leave to Drs. Fauci and Redman.

**NYT Sunday Review** has three articles on what to do re: COVID-19. All have valid recommendations because they have historical precedent or are common sense recommendations that don't require an M.D. or D.O. or Ph.D. I will list the 'best' recommendations in my opinion from each of the articles:

*'To Take on the Coronavirus, Go Medieval on It'*. See: <https://www.nytimes.com/2020/02/28/sunday-review/coronavirus-quarantine.html>

McNeil, Jr. recommends kindly quarantines of the infected, **keeping ships offshore for 20 days before docking ( or tendering freight to port and keeping crews/officers on ships offshore)**, following the action plan of Dr. Max Starkloff in 1918 Influenza Epidemic for Saint Louis, and Dr. Howard Markel for the Cholera Epidemic in 1892. Both doctors prevented Influenza and Cholera epidemics in Saint Louis and U.S.

*'Global Pandemic Warnings Ignored'* See: <https://www.nytimes.com/2020/02/29/opinion/sunday/coronavirus-usa.html>

Editorial says: plan and prepare, invest in local health departments (less politics in local than national), fund federal agencies, and forget isolationism (isolationism is a political word and divisive-I would say as Bill Gates said in NEJM Perspective-get global with the response).

**Give Dr. Fauci and Redman carte blanche re: money needed for expenses to stop an epidemic in U.S.**

*'Is this 'the Big One'?'* See: <https://www.nytimes.com/2020/02/29/opinion/sunday/coronavirus-outbreak.html>

Kristof has some excellent recommendations that I believe should take effect TODAY: **Federal government pays for any COVID-19 test and treatment. Federal government pays for any work time-off for symptoms of URI. This would be the best contact tracing we could do** (free Dx and Rx) so no one hides his/her illness and SARS-CoV-2 mild infections do not come to work (esp. doctors and nurses and HCW in hospitals) and work. The working ill are one reason the mortality rate for COVID-19 in Iran is 7% using the Iranian government's numbers.

President Trump has now got this one right: Leave it to the expert physicians and scientists. I wish the press would see the forest for the trees. Mr. Trump gets the message; get off his back.

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner*

---

**From:** Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]  
**Sent:** 3/1/2020 1:23:18 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hurst, Natalie R. EOP/OVP; (b)(6)  
**Subject:** Re: Monday - COVID19 Listening Session

Spoke with Colin. All set

Olivia Troye  
Special Advisor for Homeland Security and Counterterrorism

Office of the Vice President

Office: (b)(6)  
Mobile: (b)(6) Does not receive texts)

On Mar 1, 2020, at 1:20 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Sorry – I have been on back to back calls as has Dr. Hahn. We are on a call now, but happy to call you after?

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Sunday, March 1, 2020 1:05 PM  
**To:** Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hurst, Natalie R. EOP/OVP  
(b)(6)  
**Subject:** RE: Monday - COVID19 Listening Session

I'll call now

---

**From:** Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>  
**Sent:** Sunday, March 1, 2020 1:02 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hurst, Natalie R. EOP/OVP; (b)(6)  
**Subject:** RE: Monday - COVID19 Listening Session  
**Importance:** High

Hi all,  
I've been trying to reach Dr. Hahn on his cell. It's going to VM so he may be out of pocket.  
I tried calling Keagan as well. Can one of you please call me. (b)(6)  
Thank you,  
Olivia

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Saturday, February 29, 2020 8:36 PM  
**To:** Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Monday - COVID19 Listening Session

Hi Olivia –

FDA Commissioner Hahn asked me to reach out regarding the pharma meeting he will be attending with POTUS on Monday.

(b)(5)

Thank you

Anand

Anand Shah, MD  
Deputy Commissioner for Medical and Scientific Affairs  
U.S. Food and Drug Administration

**PRE-DECISIONAL, CONFIDENTIAL**

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/1/2020 3:48:43 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: QUOTE

Good and thanks

Sent from my iPad

On Mar 1, 2020, at 3:47 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

New quote. Getting it back to HHS now.

---

**From:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
**Sent:** Sunday, March 1, 2020 3:47 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** QUOTE

Ok?

(b)(5)

**Stephanie Caccamo**

*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.348.1956  
Cell: (b)(6)  
[stephanie.caccamo@fda.hhs.gov](mailto:stephanie.caccamo@fda.hhs.gov)

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>





---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/1/2020 5:22:04 PM  
**To:** Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Follow up for the Coronavirus task force

(b)(5)

Sent from my iPad

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/1/2020 6:22:10 PM  
**To:** Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]  
**Subject:** Re: FYI: WH Coronavirus Task Force Meeting Readout -Hahn edits

(b)(5)

Sent from my iPad

On Mar 1, 2020, at 6:18 PM, Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov> wrote:

Olivia Troye  
Special Advisor for Homeland Security and Counterterrorism  
Office of the Vice President

(b)(6)

Begin forwarded message:

**From:** "Devin.O'Malley@treasury.gov" <Devin.O'Malley@treasury.gov>  
**Date:** March 1, 2020 at 6:11:34 PM EST  
**To:** "Devin.O'Malley@treasury.gov" <Devin.O'Malley@treasury.gov>  
**Cc:** "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>, "Short, Marc T. EOP/OVP"

(b)(6)

**Subject: FYI: WH Coronavirus Task Force Meeting Readout**

All- The following readout will go out at 6:45 pm EST. (b)(5)

**A readout from the Task Force:**

(b)(5)

**(b)(5)**

###

---

**From:** Janet Moran (b)(6)  
**Sent:** 3/1/2020 9:24:59 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]  
**Subject:** March 3rd Hearing - US Response to Covid AND Covid-19 and the Americans with Disabilities Act Pandemic Law

Dr. Hahn,

I am contacting you on behalf of the people (b)(6) who is one of the high-risk groups for Covid-19. The President said if you are healthy, you'll probably be ok. What about the rest of the people in the 6 to 7 high-risk groups? Some people are in more than 1 or 2 of these groups. Don't they count or are we going to allow culling or genocide?

The American Disabilities Act's Pandemic Law states that some of the people in these groups do not have to risk their health or lives if a pandemic is declared, some very sick people are allowed by law under certain conditions, to stay home and protect their lives and health. I know the WHO will decide if Covid is a pandemic, but if Pres. Trump decides to put big business' interests over the people covered by the ADA law during a pandemic and decides it is not serious enough because "if you're healthy you'll probably be ok", People Will Die in these groups as was the case in Washington State.

**I am asking you to advocate for these people (b)(6) not only during the March 3<sup>rd</sup> hearing but throughout the cycle of the virus. Corona could be deadly in instances such as these. The CDC medical experts should be in charge and allowed to inform us directly not Donald Trump or Mike Pence who have no medical expertise.**

Thanking you in advance,

Janet Moran

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 3/1/2020 10:10:19 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** FW: FOOU INFORMATION

FYI

-----Original Message-----

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>  
Sent: Sunday, March 1, 2020 12:18 PM  
To: Farley, John <John.Farley@fda.hhs.gov>  
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>  
Subject: RE: FOOU INFORMATION

John,

Providing information so our FDA colleagues for transparency.

During our initial discussions with the company, they indicated they had (b)(4)

(b)(4)

Gary

Gary L. Disbrow Ph.D.  
Deputy Assistant Secretary  
Director, Medical Countermeasure Programs Biomedical Advanced Research and Development Authority BARDA  
Assistant Secretary for Preparedness and Response ASPR Department of Health and Human Services  
330 Independence Avenue, S.W. Room 640 G Washington, D.C. 20201  
Office: 202-260-0899  
Mobile: (b)(6)  
Fax: 202-205-0873  
email: Gary.Disbrow@HHS.gov

Legally Privileged - This e-mail transmission and any documents attached to it may contain information that is legally privileged. If you are not the intended recipient, or a person responsible for delivering this transmission to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or use of this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify the sender and destroy the original transmission, attachments, and destroy any hard copies.

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

-----Original Message-----

From: Farley, John <John.Farley@fda.hhs.gov>

Sent: Sunday, March 1, 2020 11:50 AM

To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>

Cc: Jonas, Seth H. EOP/NSC [REDACTED] (b)(6); Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Beigel, John (NIH) [E] <jbeigel@niaid.nih.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>

Subject: RE: FDA Remdesivir Access Options document

FDA has been asking folks to route through Michael Mair for coordination reasons. I updated my contact below with cell as a backup.

(b)(5)

John Farley

Office Phone 301-796-4978

Cell: [REDACTED] (b)(6)

-----Original Message-----

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

Sent: Sunday, March 1, 2020 11:26 AM

To: Farley, John <John.Farley@fda.hhs.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>

Cc: Jonas, Seth H. EOP/NSC [REDACTED] (b)(6); Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Lane, Henry C (NIH) <clane@niaid.nih.gov>; Beigel, John H (NIH) <jbeigel@niaid.nih.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: Re: FDA Remdesivir Access Options document

John,

Thank you. This is very helpful on many levels for many ongoing internal discussions. We will reach out quickly if more information is needed. Is it safe to assume that either you or Michael Mair will be FDA POC on any related questions or do you have a different POC?

Thank you, Rick

On 3/1/20, 11:12 AM, "Farley, John" <John.Farley@fda.hhs.gov> wrote:

Rick and Sally:

Please find attached a document summarizing access options from the FDA perspective. Along with our technical folks, Don Beers of our Chief Counsel's Office and Michael Mair, Director (Acting) OCET helped to prepare. Let us know if you need more. Thanks

John Farley

Office Phone 301-796-4978

-----Original Message-----

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

Sent: Saturday, February 29, 2020 4:03 PM

To: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>

Cc: Jonas, Seth H. EOP/NSC [REDACTED] (b)(6); Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Lane, Henry C (NIH) <clane@niaid.nih.gov>; Beigel, John H (NIH) <jbeigel@niaid.nih.gov>; Farley, John <John.Farley@fda.hhs.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>

Subject: Re: Remdisvir and COVID-19

ALCON,

The remdesivir protocol for the ongoing randomized clinical trial is lead by the NIH- NIAID. I've copied drs hilary Marston, Cliff Lane and john Beigel to respond to this request.

I'd the drug is being requested outside of the NIH-lead RCT, requests go to FDA for consideration. I've copied Dr John Farley at FDA to respond to those questions.

ASPR/BARDA Has representation on the clinical trials task force. I've copied Dr Bob Walker for that connection. However, these specifics would be best addressed by NIH-NIAID and or FDA.

Thanks. Rick

> On Feb 29, 2020, at 3:56 PM, Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov> wrote:

>

> Hi Seth.

>

> I have copied our BARDA team. I believe they have this information.

>

> Sally

>

> Sent from my iPhone

>

>> On Feb 29, 2020, at 3:52 PM, Jonas, Seth H. EOP/NSC (b)(6) wrote:

>>

>> Dear Sally,

>>

>> This weekend, I am working to develop a document that succinctly identify options and course of actions for Remdisvir to inform the WMD PCC and the WHTF.

>>

>> Do you have any documents or white papers that delineate the following for Remdisvir as a potential treatment COVID-19 :

**(b)(5)**

>> My understanding is that ASPR has a white paper in the works on that may cover these.

>>

>> Thanks,

>> Seth.

>>



---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 3/1/2020 10:34:35 PM  
**To:** Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Natalie Hurst [natalie.hurst@hq.dhs.gov]  
**Subject:** RE: Monday - COVID19 Listening Session

Thanks, Olivia!

---

**From:** Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>  
**Date:** March 1, 2020 at 8:46:54 PM EST  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Natalie Hurst <natalie.hurst@hq.dhs.gov>  
**Subject:** RE: Monday - COVID19 Listening Session

Hi all,  
First- Thank you for the comraderie and partnership.  
Second- I think you're all set for tomorrow. If something happens feel free to reach out.  
Best,  
Olivia (And Natalie who keeps me in check!)

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Sunday, March 1, 2020 7:41 AM  
**To:** Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Natalie Hurst <natalie.hurst@hq.dhs.gov>  
**Subject:** RE: Monday - COVID19 Listening Session

Thank you, Olivia. Colin Rom will reach out this morning to coordinate  
Anand

---

**From:** Troye, Olivia EOP/NSC <Olivia.Troye@nsc.eop.gov>  
**Sent:** Saturday, February 29, 2020 9:11 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Natalie Hurst <natalie.hurst@hq.dhs.gov>  
**Subject:** Re: Monday - COVID19 Listening Session

Hello,  
Thank you for reaching out.

(b)(5)

Adding

Natalie for SA in case anything comes up logistically.

The meeting will take place at 3:30pm on Monday. We will get him cleared into the bldg.

Would love to get some talking points and any input you'd like to send. Additionally, the agenda and memo is still being worked but we will get it to you once it's done!

Thank you,  
Olivia

Olivia Troye  
Special Advisor for Homeland Security and Counterterrorism  
Office of the Vice President  
Office: (b)(6)  
Mobile: (b)(6) (Does not receive texts)

On Feb 29, 2020, at 8:36 PM, Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)> wrote:

Hi Olivia –

FDA Commissioner Hahn asked me to reach out regarding the pharma meeting he will be attending with POTUS on Monday.

(b)(5)

Thank you

Anand

Anand Shah, MD  
Deputy Commissioner for Medical and Scientific Affairs  
U.S. Food and Drug Administration

**PRE-DECISIONAL, CONFIDENTIAL**

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 3/1/2020 11:38:10 PM  
**To:** 2019-nCoV FDA AEG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90a8a349895045e0bc4d5dc712729931-2019-nCoV F]  
**Subject:** Coronavirus may have spread in Washington state for weeks, gene sequencing suggest

<https://www.nytimes.com/2020/03/01/health/coronavirus-washington-spread.html>

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 3/2/2020 2:02:27 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: CDC lab standards

Looks like there were a number of other emails that came in over the weekend to that address from Dr. Redfield and others. Going through them now.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, March 2, 2020 1:24 PM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** RE: CDC lab standards

Thanks Heidi – I already sent him the corrected email address.

(b)(5)

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Sent:** Monday, March 2, 2020 1:07 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: CDC lab standards

Here is a suggested response to Dr. Redfield.

(b)(5)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, March 2, 2020 12:24 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: CDC lab standards

Thanks. Can someone provide assistance for my response?  
S

Sent from my iPad

On Mar 2, 2020, at 12:16 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

FYI – I will send him your correct email address.

---

**From:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Sent:** Monday, March 2, 2020 12:14 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Subject:** FW: CDC lab standards

This came to the FDA main box on Friday.

---

**From:** Redfield, Robert R (CDC) <olx1@cdc.gov>  
**Sent:** Friday, February 28, 2020 12:47 PM  
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Berger, Sherri (CDC) <sob8@cdc.gov>; Campbell, Amanda (CDC) <ons3@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>  
**Subject:** CDC lab standards

Dear Steve,

Below are CDC standards on laboratory safety.

CDC recommendations and specific guidance for handling clinical and laboratory specimens can be found at: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

In summary:

- The routine processing of clinical diagnostic specimens may be performed in BSL-2 facilities using standard BSL-2 work practices (directional airflow in the room is not a requirement for BSL2).
  - This work should be performed in a certified Class II Biological Safety Cabinet (BSC).
- Virus propagation and manipulation of virus cultures requires BSL-3 conditions require a room with directional airflow.
  - Specifically: Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens are not recommended at this time, except in a BSL3 laboratory using BSL3 work practices.
- Site specific risk assessments may indicate additional precautions be applied.

Peace,

R3

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/2/2020 2:46:46 PM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]  
**Subject:** RE: FDA Remdesivir Access Options document  
**Attachments:** TPs\_02 MAR 2020.docx

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Monday, March 2, 2020 2:41 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Subject:** RE: FDA Remdesivir Access Options document

+Carly

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, March 2, 2020 8:27 AM  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Re: FDA Remdesivir Access Options document

+ Anand  
Let's discuss this morning  
Thx  
S

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Date:** March 1, 2020 at 10:12:10 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** FW: FDA Remdesivir Access Options document

FYI

-----Original Message-----

**From:** Farley, John <John.Farley@fda.hhs.gov>  
**Sent:** Sunday, March 1, 2020 11:50 AM  
**To:** Bright, Rick (OS) <Rick.Bright@hhs.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>  
**Cc:** Jonas, Seth H. EOP/NSC; (b)(6); Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Johnson,

Robert (OS) <[Robert.Johnson@hhs.gov](mailto:Robert.Johnson@hhs.gov)>; Marston, Hilary D (NIH) <[hilary.marston@nih.gov](mailto:hilary.marston@nih.gov)>; Lane, Henry C (NIH) <[clane@niaid.nih.gov](mailto:clane@niaid.nih.gov)>; Beigel, John H (NIH) <[jbeigel@niaid.nih.gov](mailto:jbeigel@niaid.nih.gov)>; Walker, Robert (OS) <[Robert.Walker@hhs.gov](mailto:Robert.Walker@hhs.gov)>; Beers, Donald <[Donald.Beers@fda.hhs.gov](mailto:Donald.Beers@fda.hhs.gov)>; Mair, Michael <[Michael.Mair@fda.hhs.gov](mailto:Michael.Mair@fda.hhs.gov)>  
Subject: RE: FDA Remdesivir Access Options document

FDA has been asking folks to route through Michael Mair for coordination reasons. I updated my contact below with cell as a backup.

(b)(5)

John Farley  
Office Phone 301-796-4978  
Cell: (b)(6)

-----Original Message-----

From: Bright, Rick (OS/ASPR/BARDA) <[Rick.Bright@hhs.gov](mailto:Rick.Bright@hhs.gov)>  
Sent: Sunday, March 1, 2020 11:26 AM  
To: Farley, John <[John.Farley@fda.hhs.gov](mailto:John.Farley@fda.hhs.gov)>; Phillips, Sally (OS) <[Sally.Phillips@hhs.gov](mailto:Sally.Phillips@hhs.gov)>  
Cc: Jonas, Seth H. EOP/NSC: (b)(6); Disbrow, Gary (OS) <[Gary.Disbrow@hhs.gov](mailto:Gary.Disbrow@hhs.gov)>; Johnson, Robert (OS) <[Robert.Johnson@hhs.gov](mailto:Robert.Johnson@hhs.gov)>; Marston, Hilary D (NIH) <[hilary.marston@nih.gov](mailto:hilary.marston@nih.gov)>; Lane, Henry C (NIH) <[clane@niaid.nih.gov](mailto:clane@niaid.nih.gov)>; Beigel, John H (NIH) <[jbeigel@niaid.nih.gov](mailto:jbeigel@niaid.nih.gov)>; Walker, Robert (OS) <[Robert.Walker@hhs.gov](mailto:Robert.Walker@hhs.gov)>; Beers, Donald <[Donald.Beers@fda.hhs.gov](mailto:Donald.Beers@fda.hhs.gov)>; Mair, Michael <[Michael.Mair@fda.hhs.gov](mailto:Michael.Mair@fda.hhs.gov)>  
Subject: Re: FDA Remdesivir Access Options document

John,

Thank you. This is very helpful on many levels for many ongoing internal discussions. We will reach out quickly if more information is needed. Is it safe to assume that either you or Michael Mair will be FDA POC on any related questions or do you have a different POC?

Thank you, Rick

On 3/1/20, 11:12 AM, "Farley, John" <[John.Farley@fda.hhs.gov](mailto:John.Farley@fda.hhs.gov)> wrote:

Rick and Sally:

Please find attached a document summarizing access options from the FDA perspective. Along with our technical folks, Don Beers of our Chief Counsel's Office and Michael Mair, Director (Acting) OCET helped to prepare. Let us know if you need more. Thanks

John Farley  
Office Phone 301-796-4978

-----Original Message-----

From: Bright, Rick (OS/ASPR/BARDA) <[Rick.Bright@hhs.gov](mailto:Rick.Bright@hhs.gov)>  
Sent: Saturday, February 29, 2020 4:03 PM  
To: Phillips, Sally (OS) <[Sally.Phillips@hhs.gov](mailto:Sally.Phillips@hhs.gov)>  
Cc: Jonas, Seth H. EOP/NSC: (b)(6); Disbrow, Gary (OS) <[Gary.Disbrow@hhs.gov](mailto:Gary.Disbrow@hhs.gov)>; Johnson, Robert (OS) <[Robert.Johnson@hhs.gov](mailto:Robert.Johnson@hhs.gov)>; Marston, Hilary D (NIH) <[hilary.marston@nih.gov](mailto:hilary.marston@nih.gov)>; Lane, Henry C (NIH) <[clane@niaid.nih.gov](mailto:clane@niaid.nih.gov)>; Beigel, John H (NIH) <[jbeigel@niaid.nih.gov](mailto:jbeigel@niaid.nih.gov)>; Farley, John <[John.Farley@fda.hhs.gov](mailto:John.Farley@fda.hhs.gov)>; Walker,

Robert (OS) <[Robert.Walker@hhs.gov](mailto:Robert.Walker@hhs.gov)>

Subject: Re: Remdesivir and COVID-19

ALCON,

The remdesivir protocol for the ongoing randomized clinical trial is lead by the NIH- NIAID. I've copied drs hilary Marston, Cliff Lane and john Beigel to respond to this request.

I'd the drug is being requested outside of the NIH-lead RCT, requests go to FDA for consideration. I've copied Dr John Farley at FDA to respond to those questions.

ASPR/BARDA Has representation on the clinical trials task force. I've copied Dr Bob Walker for that connection. However, these specifics would be best addressed by NIH-NIAID and or FDA.

Thanks. Rick

> On Feb 29, 2020, at 3:56 PM, Phillips, Sally (OS/ASPR/SPPR) <[Sally.Phillips@hhs.gov](mailto:Sally.Phillips@hhs.gov)> wrote:

>

> Hi Seth.

>

> I have copied our BARDA team. I believe they have this information.

>

> Sally

>

> Sent from my iPhone

>

>> On Feb 29, 2020, at 3:52 PM, Jonas, Seth H. EOP/NSC: (b)(6) wrote:

>>

>> Dear Sally,

>>

>> This weekend, I am working to develop a document that succinctly identify options and course of actions for Remdesivir to inform the WMD PCC and the WHTF.

>>

>> Do you have any documents or white papers that delineate the following for Remdesivir as a potential treatment COVID-19 :

>>

**(b)(5)**

>> My understanding is that ASPR has a white paper in the works on that may cover these.

>>

>> Thanks,

>> Seth.

>>



---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 3/2/2020 2:54:23 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]  
**Subject:** HELP oral testimony  
**Attachments:** 2020.03.01 CORONA VIRUS ORAL TESTIMONY FDA FINAL CLEAN.docx

Hi Dr. Hahn-

Attached is the oral testimony that you have in your binder. We highlighted a couple areas to confirm before tomorrow morning. This is based on IMG cleared language and your member briefing TPs and is OCC cleared. Let us know if you want to work through any changes.

Thanks,  
Karas

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 3/2/2020 5:53:07 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** FW: [EXTERNAL] WSJ request for comment on coronavirus testing

Can we chat about the highlighted below?

---

**From:** Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>  
**Sent:** Monday, March 2, 2020 4:03 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: [EXTERNAL] WSJ request for comment on coronavirus testing

Sent from my iPhone

Begin forwarded message:

**From:** "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>  
**Date:** March 2, 2020 at 3:53:58 PM EST  
**To:** "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Oakley, Caitlin B. (OS/ASPA)" <Caitlin.Oakley@HHS.GOV>, "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>  
**Cc:** "Devin.O'Malley@treasury.gov" <Devin.O'Malley@treasury.gov>  
**Subject:** Fwd: [EXTERNAL] WSJ request for comment on coronavirus testing

I have no background on this (b)(5)

Sent from my iPhone

Begin forwarded message:

**From:** "Restuccia, Andrew" <andrew.restuccia@wsj.com>  
**Date:** March 2, 2020 at 3:13:48 PM EST  
**To:** "Deere, Judd P. EOP/WHO" <Judson.P.Deere@who.eop.gov>, "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>, "Devin.omalley@treasury.gov" <Devin.omalley@treasury.gov>, "Grisham, Stephanie A. EOP/WHO" (b)(6) "Gidley, Hogan H. EOP/WHO" (b)(6)  
**Subject:** [EXTERNAL] WSJ request for comment on coronavirus testing

Hi everybody.

We're writing a story about the backstory on the decision to send the initial defective coronavirus tests to states and public health labs. My colleagues have been digging into this, and they've been told there was a conference call earlier this month with senior administration officials, including Azar, his chief of staff, Brian Harrison, Stephan Hahn, Anthony Fauci, Jeffrey Shuren, Robert Redfield and Anand Shah.

On the call, Harrison and Azar were warned that the tests were potentially compromised, and Harrison ordered them to be shipped anyway.

We're told that Hahn, Fauci, Shuren and Shah all raised concerns about the tests on the call. Harrison decided to move forward with shipping the tests even after Shuren gave a 20-minute argument about the seriousness of the contamination.

We're already talking to HHS, but we wanted to reach out to the White House about this as well to see if you have any comment, and to check in to see if the president still has confidence in Mr. Azar.

We've been told this story is competitive, so we're hoping to publish later today.

Andrew Restuccia

WHITE HOUSE REPORTER, WASHINGTON BUREAU



M: (b)(6)

E: [andrew.restuccia@wsj.com](mailto:andrew.restuccia@wsj.com) | T: @andrewrestuccia

A: 1025 Connecticut Ave. NW, Suite 800 | Washington, D.C. 20036



Sign up for WSJ's free Capital Journal newsletter [here](#).

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 3/2/2020 8:53:56 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]  
**Subject:** Hearing questions  
**Attachments:** Polling Questions and Answers.docx

As we discussed, attached are the questions we're hearing that you may get tomorrow. Some will be directed at other witnesses as well, but we've included answers that you can give from the FDA perspective.

If we receive more, we'll send on this email chain.

Thanks,

Karas

Internal, confidential, pre-decisional

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/3/2020 6:42:45 AM  
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**Subject:** Re: Coronavirus testing

Thanks

Sent from my iPad

On Mar 2, 2020, at 3:26 PM, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Commissioner Hahn and Keagan,

Please see the response below. Emer is double checking, but in short, it seems like there is not a WHO developed or sponsored test at this point.

Please let me know if you have any questions.

Best Regards,  
Peter

---

**From:** COOKE, Emer <cooke@who.int>  
**Sent:** Monday, March 2, 2020 3:15 PM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Cc:** Raychaudhuri, Gopa <Gopa.Raychaudhuri@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Subject:** Re: Coronavirus testing

Dear Peter,

Do you know where this information is coming from? We certainly haven't developed a test, and, as far as I am aware, we haven't listed one either. We did announce Friday that the Emergency Use Listing procedure would be open to candidate IVDs to detect SARS-CoV-2 Nucleic acid.

I am enquiring with other colleagues just in case I missed something in another part of the organisation.

Best wishes,  
Emer

Emer Cooke  
Director Regulation and Prequalification Department (RPQ) WHO

(b)(6)

Sent from my mobile device, please excuse brevity and typos

On 2 Mar 2020, at 20:39, Marks, Peter <Peter.Marks@fda.hhs.gov> wrote:

Dear Emer,

My apologies if this is a duplicate email. I was having some connectivity issues on my phone and am now on my laptop.

There has been some confusion here regarding WHO and coronavirus testing. Is there an actual WHO developed test, or is WHO simply endorsing or listing the use of other tests? I suspect the latter, but Jeff Shuren, the head of devices at FDA and I would like to confirm. Thanks so much for your help clarifying this. (Also, so sorry that the predictions that we spoke of seem to be coming true.)

Best Regards,  
Peter

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 3/3/2020 7:07:22 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: NYT on Issues with COVID-19 Testing

See below. Think we covered this but to be safe.

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Sent:** Tuesday, March 3, 2020 6:38 AM  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Fwd: NYT on Issues with COVID-19 Testing

Forwarding because I think there is a high chance a question (b)(5)

I think all he needs to say is:

**(b)(5)**

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Date:** March 2, 2020 at 11:09:11 PM EST  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Subject:** Re: NYT on Issues with COVID-19 Testing

The WHO statement is not correct. A German university lab posted online a protocol for a test on January 16th. The CDC posted its protocol on January 24th. The WHO has posted the German, US CDC, and a handful of other protocols on its website as a reference for test developers to use if they so choose. The WHO has not developed, distributed, or listed any test. This was confirmed by Emer Cooke, Director of Regulation and Prequalification at WHO.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Date:** March 2, 2020 at 9:34:07 PM EST  
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Subject:** NYT on Issues with COVID-19 Testing

FYI on the piece below from the NYT re problems with COVID-19 testing.

It asserts that Germany developed a test that, if CDC had adopted it, FDA could have approved it and it could have been used (and that it could still be used even now).

It also says FDA broke the logjam in delays/lack of testing capacity in the U.S.

Best,

Jennifer

<https://www.nytimes.com/2020/03/02/health/coronavirus-testing-cdc.html>

## ***As Coronavirus Numbers Rise, C.D.C. Testing Comes Under Fire***

Federal health officials botched an initial diagnostic test and restricted widespread screening. Missteps may have raised the risks to Americans, critics say.

By **Roni Caryn Rabin**, **Knvul Sheikh** and **Katie Thomas**

• March 2, 2020 Updated 7:48 p.m. ET

The coronavirus has found a crack in the nation's public health armor, and it is not one that scientists foresaw: diagnostic testing.

The Centers for Disease Control and Prevention botched its first attempt to mass produce a diagnostic test kit, a discovery made only after officials had shipped hundreds of kits to state laboratories.

A promised replacement took several weeks, and still did not permit state and local laboratories to make final diagnoses. And the C.D.C. essentially ensured that Americans would be tested in very few numbers by imposing stringent and narrow criteria, critics say.

On Monday, following mounting criticism of the federal response, Trump administration officials promised a rapid expansion of the country's testing capacities. With the help of private companies and academic centers, as many as a million diagnostic tests could be administered by the end of this week, said Dr. Stephen Hahn, commissioner of the Food and Drug Administration.

But many scientists wonder if the moves come too late.

As of Monday afternoon, 100 Americans were infected with the coronavirus in the United States. Six deaths have been reported. Dozens of patients, in several states, may have caught the virus in their communities, suggesting that pathogen already may be circulating locally.

The case numbers are rising not just because the virus is spreading, but because federal officials have taken steps toward expanded testing. The persistent drumbeat of positive test results has raised critical questions about the government's initial management of the outbreak.

Why weren't more Americans tested sooner? How many may be carrying the virus now?

Most disturbing of all: Did a failure to provide adequate testing give the coronavirus time to gain a toehold in the United States?

"Clearly, there have been problems with rolling out the test," said Dr. Thomas Frieden, former director of the C.D.C. "There are a lot of frustrated doctors and patients and health departments."

Still, Dr. Frieden said he thought the situation was improving. Other experts, although supportive of the agency, were mystified that federal officials could have committed so many missteps.

"The incompetence has really exceeded what anyone would expect with the C.D.C.," said Dr. Michael Mina, an epidemiologist at Harvard University. "This is not a difficult problem to solve in the world of viruses."

Officials at the C.D.C. did not respond to repeated requests for comment. The agency abruptly canceled a news conference on Monday just as it was to begin. Officials appeared to have removed figures on the agency website counting how many Americans had been tested.



In February, the C.D.C. rolled out a three-step diagnostic test and distributed testing kits — each of which could run about 800 tests — to state and local health laboratories. But some of the components of the diagnostic kits were flawed, and produced inconclusive results.

A three-step replacement was promised but never arrived; the agency has not fully explained why, except to say that there was a manufacturing defect. As a result, diagnostic testing was only conducted at the agency's labs in Atlanta.

The C.D.C. eventually rolled out a two-step replacement and permitted a few laboratories, where the kits had been working, to continue using their tests. But those with only one working component of the test still could not diagnose patients on their own.

Getting results from the C.D.C. took days, however, and in any event the criteria for testing were strict — among them, the patient must have had recent travel to China or contact with someone known to be infected.

Doctors nationwide complained of a bottleneck, both because of the restrictive test criteria and because of the agency's limited testing capacity. The agency said it had the capacity to test about 400 specimens a day.

The test criteria were “too stringent, and people aren't getting tested,” said Lauren M. Sauer, an assistant professor of emergency medicine at Johns Hopkins Medicine.

“I've heard from so many colleagues that tests were turned down,” she added.

By the end of last week, as the first cases of possible community transmission began to emerge in California and Washington State, the C.D.C. broadened the number of patients who qualified for testing to include travelers returning from places like South Korea and Italy, and hospitalized patients who were very ill and whose symptoms could not be otherwise explained.

“We have been really frustrated, because one of the things that is a hallmark of public health labs is that we are usually ‘ready, set, go,’ and here we were — ‘ready, set, wait,’” said Scott Becker, chief executive of the Association of Public Health Laboratories.

Late last week, the Food and Drug Administration broke the logjam, authorizing state and local laboratories to do initial testing on their own. If labs had developed and validated a test, they could use it for diagnosis instead of relying on the C.D.C.'s version or waiting for a replacement.

The move greatly expanded the nation's testing capacity, and the C.D.C. also said it was shipping out new test kits to the states as well.

At the time, however, the agency had tested just under 500 Americans with suspected infections identified by public health officials in the United States.

Other nations have tested patients by tens of thousands. China has probably tested millions.

“How come the South Koreans can do 10,000 tests a day and we can't?” said Ralph Baric, who studies coronaviruses and emerging diseases at University of North Carolina.

“Once you knew you had asymptomatic spread and community spread in China, why is it that the United States of America hasn't created tens of thousands of tests?”

## **‘We Can't Get Tested’**

Soon after the virus surfaced in China, the C.D.C. got to work on its own test. “Generally, C.D.C. provides these tests for the world,” said Dr. Frieden.

But German researchers were devising their own test, which was quickly adopted by the World Health Organization for distribution around the world.

After the C.D.C.'s version turned out to be flawed, the agency continued to pursue it, despite the fact that another diagnostic test was already in wide use.

With F.D.A. approval, the agency could simply have distributed the test used by the W.H.O. instead of creating a new one from scratch, Dr. Mina said. The government could do so even now.

"It's just a very American approach to say, 'We're the U.S., the major U.S. public health lab, and we're going to not follow the leader,'" Dr. Mina said.

New kits were released over the past weekend, and more are on the way, Alex M. Azar II, the secretary of health and human services, said on Sunday.

The demand for testing is continuing to grow.

"It seems like we can't get tested," complained Jennifer Knight of Queens, who returned with her partner and a group of friends more than a week ago from Milan, near where the virus is spreading.

Several members of the group had fallen ill, either in Milan or since returning, four members of the group said in interviews. Ms. Knight has had migraines and a sore throat, but her partner has had a fever and a bad cough as well.

Staff at an urgent care clinic told her over the phone that they did not do coronavirus testing. So did a hospital in Brooklyn.

"Whenever we make an attempt to get tested, we're pushed out the door," she said. She and her partner are now largely self-quarantined in her apartment.

In Rhode Island, Onésimo T. Almeida, an author and professor at Brown University, had been coughing, sneezing and registering a fever for nearly a week after returning home to Providence from a conference in Portugal. A friend of his who attended had later tested positive for the virus.

But when Professor Almeida called the Rhode Island Department of Health and asked to be tested, he was told that he did not fit the criteria to be screened.

On Monday, however, the health department called Dr. Almeida and asked him to drive to a hospital, where medical staff would get into his car in the afternoon and test him after all — in the parking lot.

A doctor swabbed his mouth, nose and throat through the driver's side window, in what he imagined looked like a drunk-driving test.

He is now waiting for the test results. "I'm looking forward to getting back to teaching, and I'm looking forward to going outside," he said.

Testing may well become more widespread in the next few weeks. But that may not help contain the coronavirus if it is being spread by people who are asymptomatic.

"There has been a silent epidemic of Covid-19 in the United States that is not going to be silent any longer," said Michael Osterholm, an epidemiologist at the University of Minnesota, referring to the official name of the coronavirus illness.

"Testing will show it. This is not a surprise — it shouldn't have been."

Reporting was contributed by Nicholas Bogel-Burroughs and Joseph Goldstein in New York.

Katie Thomas covers the business of health care, with a focus on the drug industry. She started at The Times in 2008 as a sports reporter. [@katie\\_thomas](https://twitter.com/katie_thomas)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/3/2020 8:45:33 AM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Fwd: Requested information

In case you are asked

Sent from my iPad

Begin forwarded message:

**From:** "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>  
**Date:** March 3, 2020 at 8:40:40 AM EST  
**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Subject:** **FW: Requested information**

---

Here's the performance data that was in the original validation data set. You'll see the number of samples are small. For LoD, the CDC test can identify down to essentially 2 viruses per reaction. As you know, the actual patient sample will have more virus but you only test some of the sample. (b)(5)

(b)(5)

**From:** Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>  
**Sent:** Tuesday, March 3, 2020 8:34 AM  
**To:** Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>  
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Subject:** RE: Requested information

Thanks Uwe! Jeff, I have rearranged the information

### **CDC EUA Coronavirus Test Performance**

**Bottom Line:** The FDA believes the sensitivity of the assay is excellent and capable of detecting low levels of virus. Analytical data submitted to the FDA by the CDC demonstrated that the assays detect **between 2 and 5 spiked in RNA copies per test**.

#### **Background:**

Based on limited clinical data, the clinical performance is:

Positive percent agreement (Sensitivity) = 13/13 = 100% (95% CI: 77.2% - 100%)

Negative percent agreement (Specificity) = 104/104 = 100% (95% CI: 96.4% - 100%)

Negative or positive predictive values could not be calculated since were not prospective collected data.

The review division concluded that the test is a well performing test with acceptable performance, and the outbreak situation the benefit to use the test outweigh the risk

Best,  
*Tim*

**Timothy T. Stenzel, MD, PhD**

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health  
Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health**

**U.S. Food and Drug Administration**

[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)

**Jennifer Campbell**

*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-7692

[Jennifer.Campbell@fda.hhs.gov](mailto:Jennifer.Campbell@fda.hhs.gov)

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:  
<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 3/3/2020 9:41:52 AM  
**To:** Williams, James H. EOP/WHO (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Grogan, Joseph J. EOP/WHO (b)(6)  
**CC:** Baehr, James S. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: Treatment Candidate for Coronavirus

James – Thanks for this additional info. We’re on it  
Anand

**From:** Williams, James H. EOP/WHO (b)(6)  
**Sent:** Tuesday, March 3, 2020 9:38 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Grogan, Joseph J. EOP/WHO (b)(6)  
**Cc:** Baehr, James S. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Treatment Candidate for Coronavirus

For awareness:

(b)(4) (b)(5)

Feel free to contact me if you have questions.

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Tuesday, March 3, 2020 9:09 AM  
**To:** Grogan, Joseph J. EOP/WHO (b)(6)  
**Cc:** Williams, James H. EOP/WHO (b)(6); Baehr, James S. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: Treatment Candidate for Coronavirus

We’re on it.  
Steve

Sent from my iPad

On Mar 3, 2020, at 7:57 AM, Grogan, Joseph J. EOP/WHO (b)(6) wrote:

Thanks. James give them whatever they need. (b)(5)  
(b)(6)

Sent from my iPhone

On Mar 3, 2020, at 6:50 AM, Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)> wrote:

James,  
We will look at it.  
Anand, will you review with Jeff?  
Thanks.  
Steve  
Sent from my iPad

On Mar 2, 2020, at 7:22 PM, Williams, James H. EOP/WHO <[REDACTED] (b)(6) > wrote:

Good evening Commissioner,

Well done at the press conference this evening.

Please see the attached document: [REDACTED] (b)(4) (b)(5)

[REDACTED] (b)(4) (b)(5)

Thank you,

James H. Williams  
Special Assistant to the President  
Domestic Policy Council  
The White House

[REDACTED] (b)(6)

[REDACTED] (b)(4) (b)(5)

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 3/3/2020 10:48:54 PM  
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**CC:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]  
**Subject:** RE: Remdesivir  
**Attachments:** RE: Remdesivir options document

Just FYI – the response below is not consistent with how we received the doc – we did not receive through Exec Sec – the request we were on went straight to FDA, BARDA, ASPR, NIH...

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Tuesday, March 3, 2020 10:29 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>  
**Subject:** FW: Remdesivir

FYI below about status of remdesivir and supply issues. Attached is an options paper with comments from Michael Mair in track changes.

---

**From:** Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>  
**Sent:** Tuesday, March 3, 2020 9:34 PM  
**To:** Sinclair, Michael R. EOP/NSC <Michael.R.Sinclair@nsc.eop.gov>; Davis, May M. EOP/WHO <May.Davis@who.eop.gov>  
**Cc:** Chang, William (OS) <William.Chang@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>  
**Subject:** Re: Remdesivir

Hi All,

(b)(5)

**(b)(5)**

Thanks,

Brian



---

**From:** McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]  
**Sent:** 3/4/2020 4:20:12 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**Subject:** Homework - 3/4  
**Attachments:** FY21 House Budget Hearing Oral Testimony--OPLIA cleared.docx; FY 2021 Master Hot Topic Q-A - FINAL.docx; Supplemental for CoronavirusOCA.docx

Hi Dr. Hahn-

Following up on our conversation earlier, attached are three items for your review this evening.








- Budget Oral statement;
- One pager on the COVID-19 supplemental (background + key messages); and
- Appropriations hearing prep master list of Q&A.






Please let me know if you need anything else!

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 3/5/2020 12:10:12 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** 3/4-- WEDNESDAY HOMEWORK - INTERNAL CONFIDENTIAL  
**Attachments:** 2019-3548 Merkley E Cig Incoming LTR.pdf; 2019-3548 - Merkley Letter Vaping Illness CoS commnets edits OL.docx; 2019-3666 - Meuser +7 -Cigars.pdf; 2019-3666 - Meuser Multi Ltr Cigars\_ (002).docx; 2019-3666 - Cover Memo for Meuser Multi Ltr Cigars.docx; 2020-338 Incoming.pdf; 2020-338 - Engel Multi sig respoonse FDA HHS Final.docx; 2019-4188- Cover Memo for Engel multi sig respons.docx; 20200218 COVID19 Clean.docx; FY21 House Budget Hearing Oral Testimony--OPLIA cleared.docx; FY 2021 Master Hot Topic Q-A - FINAL.docx; Supplemental for CoronavirusOCA.docx

Dr. Hahn, attached for your review tonight/ tomorrow morning

- COVID-19 Op-ed
- Budget Prep Items
- Congressional Letters

ITEMS FOR YOUR REVIEW	
Action: Edit By 9:00am Thursday	<b>ITEM #1: Op-ed re: COVID-19</b>  20200218 COVID19 Clean....
Action: Edit By 9:00am Thursday	<b>ITEM #2: Budget Prep: Budget Oral statement; One pager on the COVID-19 supplemental, Appropriations hearing prep master list of Q&amp;A.</b>    FY21 House Budget Hearing ...    FY 2021 Master Hot Topic Q-A - ...    Supplemental for CoronavirusOCA...
Action: Edit By 9:00am Thursday	<b>ITEM #3: Congressional Letters</b> Rep Engel multi-sig on youth use of flavored ENDS    2019-4188- Cover Memo for Engel ...    2020-338 - Engel Multi sig respoon...    2020-338 Incoming.pdf Rep. Meuser and 7 others on premium cigars

	 2019-3666 - Cover Memo for Meuse...  2019-3666 - Meuser Multi Ltr ...  2019-3666 - Meuser +7 -Ciga...
Action: Review and Clear for Dept By 9:00am Thursday	<b>ITEM #4: Congressional Letters</b> —for clearance to go to Dept and for autopen once Dept clears  2019-3548 - Merkley Letter V...  2019-3548 Merkley E Cig Incoming L...

Thanks and have a good flight!

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/5/2020 11:31:14 AM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Follow-Up to Lab White House Meeting

I'll discuss with Seema re: (b)(5)

Sent from my iPad

On Mar 5, 2020, at 11:26 AM, Rom, Colin <Colin.Rom@fda.hhs.gov> wrote:

INTERNAL / CONFIDENTIAL

Just spoke with Julie

She forwarded this along and mentioned her members are (b)(4) They should have more complete info on this in the next day or so as more members respond and she will follow up. She understood this would likely be shared with task force but specifically asked that it not be discussed publicly at this time. Let me know if there is more info that would be helpful.

They have an issue below related to reimbursement as the CMS payment code only applies to CDC tests, not those developed by their labs. Apparently HHS has been looped in on this issue

---

**From:** Julie Khani <jkhani@acla.com>  
**Sent:** Thursday, March 5, 2020 11:15 AM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** FW: Follow-Up to Lab White House Meeting

Colin, per our conversation. Thanks!

Julie

---

**From:** Julie Khani  
**Sent:** Thursday, March 5, 2020 10:23 AM  
**To:** [joseph.j.grogan@who.eop.gov](mailto:joseph.j.grogan@who.eop.gov)  
**Cc:** Steele, Danielle (HHS/IOS) <[Danielle.Steele@hhs.gov](mailto:Danielle.Steele@hhs.gov)>  
**Subject:** Follow-Up to Lab White House Meeting

Good morning, Joe. Reaching out in follow-up to the lab meeting with Vice President Pence yesterday. I want to reemphasize that ACLA members are committed to increasing coronavirus testing capacity, and want to work closely with the CDC, FDA, public health labs, and others to move quickly. You may have seen Quest's [press release](#) this morning about launching a test, and more to come soon from other ACLA members.

ACLA and member labs have been having weekly calls with the CDC since mid-January, and many of the calls have included FDA and APHL representatives. We will continue to coordinate closely.

**Importantly, I do want to flag for you some issues with the Medicare code recently announced by CMS.** The code is specific to the CDC test. Labs that develop their own test, or utilize a test kit from a manufacturer, will be unable to use this code. A few bullet points below to explain the issue.

We've run into some challenges in discussing this with a large Medicare contractor, who is suggesting pricing the test at around \$30. This is unlikely to cover lab costs.

My cell is (b)(6) if you have questions or would like to discuss.

Thank you!

Julie

Julie Khani \ President \ ACLA \ [jkhani@acla.com](mailto:jkhani@acla.com) \ 202-637-9466 (o) (b)(6) (m)

Here's the list of issues we discussed and could use assistance with.

1. Commercial laboratories performing COVID-19 testing need either a Category 1 AMA CPT code (or) CMS HCPCS code in order to bill the LDT. (The current U0001 code assigned by CMS is only valid for the CDC's test.)
2. The code needs to be retro-active consistent with the date the commercial lab begins performing the COVID-19 testing (once the code is approved it will take a few weeks for CMS to implement the code in their systems).
3. We are requesting the rate be cross-walked to CPT 87662 which is currently priced by Medicare at \$51.31. This is the rate assigned to Zika virus which required similar development under emergency authorization.
4. In working through reimbursement with MACs we are hearing resistance from one of the larger contractors not amenable to considering the proposed pricing.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/5/2020 11:34:22 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**Subject:** Re: CDRH COVID-19 Updates

Excellent update

Sent from my iPad

On Mar 4, 2020, at 7:55 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thank you for the update. Wishing you a speedy recovery, we will try not to bother you too much.

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Sent:** Wednesday, March 4, 2020 7:10 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** CDRH COVID-19 Updates

A few items to update you on. The Nebraska Medicine Clinical Laboratory had notified us on Monday that they had validated their test and would begin testing patients. Today they submitted their EUA. The lead reviewer will provide their first assessment tomorrow afternoon or early Friday.

New York State Department of Health's Wadsworth Center told us this afternoon that they want to broaden their EUA to include other NY hospitals. That will be helpful.

Robert Ford at Abbott reached out to me. We discussed their POC influenza test and possibility of (b)(5) (b)(5) Planning for a larger group discussion on Friday.

We will hold a Webex town hall on Friday for developers to help answer technical questions about development and validation of molecular tests for SARS-CoV-2 and the recently-issued guidance.

We are working on plans for using alternatives for surgical masks and gowns. We will coordinate with CDC, OCET, and ASPR. We are looking at recommendations for use of alternative products in descending order or protection provided for providers if they cannot get access to the products they need. We anticipate it will be a public communication and information posted on our/CDC's website(s). No need for an EUA at this time.

Just a reminder that I will be (b)(6) and then will have limited ability to do email and text thereafter for at least several days/week or two plus.

**Jeffrey Shuren, MD, JD**

*Director*

**Center for Devices and Radiological Health**

**U.S. Food and Drug Administration**

Tel: 301-796-5900

Email: [jeff.shuren@fda.hhs.gov](mailto:jeff.shuren@fda.hhs.gov)

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?ID=2000&S=E>.

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 3/5/2020 1:28:44 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** FW: WHTF Briefing 03.05.2020 DRAFT.docx  
**Attachments:** WHTF Briefing 03.05.2020 DRAFT.docx

Daily update for this afternoon's task force call

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 12:37 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** WHTF Briefing 03.05.2020 DRAFT.docx

Hi [REDACTED] and should be back to send a version later that can have more up to date info, but just in case, you can send this to him if I cannot get back.



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/5/2020 2:05:13 PM  
**To:** Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: FDA Requests for CDC

Anne  
Thank you. We really appreciate your support  
Steve

---

**From:** Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>  
**Date:** March 5, 2020 at 1:00:55 PM CST  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: FDA Requests for CDC

This is a bit broader than what I spoke to the commissioner about but we are pulling more expertise so we can respond.

Get [Outlook for iOS](#)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 1:53:14 PM  
**To:** Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** FDA Requests for CDC

Hi Dr. Schuchat,

Dr. Hahn said that he spoke with you about some ideas that would help get more diagnostic tests to market. Below are some of those suggestions. We would greatly appreciate your approval.

(b)(5)

Let me know if you have questions. We greatly appreciate your help here.

Thanks,  
Keagan

---

**From:** Jon R. Cohen [JCohen@BioReference.com]  
**Sent:** 3/5/2020 2:09:43 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]  
**Subject:** follow up to white house meeting

Steve; it was great meeting you yesterday. As discussed, nice to see other physicians in significant leadership positions. I complemented your help in our press release as to test availability. (see attached) When the world calms down and we get back to some order of normalcy, maybe we can meet in DC and catch up around the industry etc. If I can be of any other help during this craziness, feel free to reach out.

<https://www.bioreference.com/opko-healths-bioreference-laboratories-to-introduce-coronavirus-disease-covid-19-test/>

Jon

Jon R. Cohen, M.D.  
Executive Chairman  
[Jcohen@bioreference.com](mailto:Jcohen@bioreference.com)  
Cell: (b)(6)  
800-229-5227 x8250

The information transmitted in this email and any of its attachments is intended only for the person or entity to which it is addressed and may contain BioReference Laboratories proprietary information, which is privileged, confidential, or subject to copyright belonging to BioReference Laboratories. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited and may be unlawful. If you received this in error, please contact the sender immediately and delete and destroy the communication and all of the attachments you have received and all copies thereof.

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 3/5/2020 3:16:50 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Fwd: UPDATED-PLEASE SEND TO HAHN  
**Attachments:** WHTF Briefing 03.05.2020 DRAFT.docx

Updated and cleared and good to go

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Date:** March 5, 2020 at 3:08:28 PM EST  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** UPDATED-PLEASE SEND TO HAHN

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 3/5/2020 3:37:46 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** FW: FDA Requests for CDC

She just gave us a name to work with. I reached out to him and nothing yet.

---

**From:** Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>  
**Sent:** Thursday, March 5, 2020 2:47 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Monroe, Stephan S (CDC) <stm2@cdc.gov>  
**Cc:** Berger, Sherri (CDC) <sob8@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>  
**Subject:** Re: FDA Requests for CDC

Steve Monroe, our associate director for laboratory science, will be our lead in working through this with you all.  
Get [Outlook for iOS](#)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 2:17 PM  
**To:** Schuchat, Anne MD (CDC/OD); Hahn, Stephen  
**Cc:** Berger, Sherri (CDC/OCOO/OD)  
**Subject:** RE: FDA Requests for CDC

Thanks Dr. Schuchat,

I asked the team to focus on the maximum steps we could take with you all to make sure we got as many tests out there as we could. That being said, what would get us the most bang would be the below:

(b)(5)

Can you all help with this? I am including Sherri as well.

Thanks,  
Keagan

---

**From:** Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>  
**Sent:** Thursday, March 5, 2020 2:01 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: FDA Requests for CDC

This is a bit broader than what I spoke to the commissioner about but we are pulling more expertise so we can respond.

Get [Outlook for iOS](#)

---

**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Sent:** Thursday, March 5, 2020 1:53:14 PM

**To:** Schuchat, Anne MD (CDC/OD) <[acs1@cdc.gov](mailto:acs1@cdc.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>

**Subject:** FDA Requests for CDC

Hi Dr. Schuchat,

Dr. Hahn said that he spoke with you about some ideas that would help get more diagnostic tests to market. Below are some of those suggestions. We would greatly appreciate your approval.

**(b)(5)**

Let me know if you have questions. We greatly appreciate your help here.

Thanks,  
Keagan

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/6/2020 9:29:32 AM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: ACLA Members Announce COVID-19 Testing

Excellent and thanks

Sent from my iPad

On Mar 5, 2020, at 5:26 PM, Rom, Colin <Colin.Rom@fda.hhs.gov> wrote:

FYI

---

**From:** Julie Khani <jkhani@acla.com>  
**Date:** March 5, 2020 at 5:15:57 PM EST  
**To:** Commissioner FDA <CommissionerFDA@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** ACLA Members Announce COVID-19 Testing

Commissioner Hahn:

It was such a pleasure to meet you yesterday, and thank you again for speaking at the annual meeting and engaging with my members during our time at the White House. I can only imagine how busy you must be, so I won't trouble you with many emails. However, in light of yesterday's discussions, I wanted to be sure you were aware of the announcements by three ACLA members today on the availability of COVID-19 testing. I expect additional announcements to be coming soon.

Look forward to continuing to coordinate with you and other members of the Task Force.

Thank you.

Julie

Julie Khani \ President \ ACLA \ [jkhani@acla.com](mailto:jkhani@acla.com) \ 202-637-9466 (o) \ (b)(6)

Quest Diagnostics:

<https://newsroom.questdiagnostics.com/2020-03-05-Quest-Diagnostics-to-Launch-Coronavirus-Disease-2019-COVID-19-Test>

LabCorp:

<https://ir.labcorp.com/news-releases/news-release-details/labcorp-launches-test-coronavirus-disease-2019-covid-19>

BioReference Laboratories

<https://finance.yahoo.com/news/opko-healths-bioreference-laboratories-introduce-173000372.html>

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/6/2020 12:58:17 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FW: LDTs and EUAs -- privileged/deliberative

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Date:** March 6, 2020 at 12:46:11 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** FW: LDTs and EUAs -- privileged/deliberative

See below on what FDA has done.

(b)(5)



---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 3/6/2020 1:08:22 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** FW: LDTs and EUAs -- privileged/deliberative

FYI

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Friday, March 6, 2020 12:22 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** FW: LDTs and EUAs -- privileged/deliberative

FYI – just spoke to Rachel re the below.

---

**From:** Amin, Stacy  
**Sent:** Friday, March 6, 2020 12:22 PM  
**To:** 'Semmel, Rachel K. EOP/OMB' <Rachel.K.Semmel@omb.eop.gov>  
**Subject:** RE: LDTs and EUAs -- privileged/deliberative

See below on what FDA has done. Pls call with any questions:

(b)(5)

---

**From:** Semmel, Rachel K. EOP/OMB [REDACTED] (b)(6)  
**Sent:** Friday, March 6, 2020 11:33 AM  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Subject:** RE: LDTs and EUAs -- privileged/deliberative

Hey, Stacy,

I'm helping Grogan and Maria on some coms, mind giving me a call?

**Rachel Semmel**

Director of Communications

The White House, Office of Management and Budget

202.456.6364 work

(b)(6) cell (Cannot receive text)

Begin forwarded message:

**From:** "Amin, Stacy" <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

**Date:** March 5, 2020 at 9:52:47 PM EST

**To:** "Bonner, Maria K. EOP/WHO" <[Maria.K.Bonner@who.eop.gov](mailto:Maria.K.Bonner@who.eop.gov)>

**Cc:** "Rom, Colin" <[Colin.Rom@fda.hhs.gov](mailto:Colin.Rom@fda.hhs.gov)>, "Lenihan, Keagan" <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, "Shah, Anand" <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>

**Subject:** LDTs and EUAs -- privileged/deliberative

(b)(5)

\*\*\*\*\*

Stacy Cline Amin  
Chief Counsel  
Food and Drug Administration  
Deputy General Counsel  
Department of Health and Human Services

**From:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]  
**Sent:** 3/6/2020 1:14:08 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe193caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Chaput, Daniel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6aee5b76fbac46349df3dbedb2e77511-HHS-Daniel.]; Johnson, Lynn (ACF)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Nicholls, Richard (ACL)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baae1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86ebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Ethier, Kathleen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7895b283237401cb312576b43fef452-HHS-kbe0-cd]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Brookes, Brady (CMS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Hahn, Stephen

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Macrae, Jim (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Disbrow, Gary (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Mark.g.hartell.mil@mail.mil; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbef326c5e670d41c-HHS-Jonatha]; Cooper, Kevin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; DeBord, Kristin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Gin, Julia (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Dodgen, Daniel (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Gettinger, Andrew (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17c5a2d5b6284d2ca58f9de61500f3fe-HHS-Andrew.]; Abbey, Rachel (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e829e079e04eb48bdb70b832423c8f-HHS-Rachel.]; Lennon, Todd (HRSA)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96a7c26cba7943b2b2f9c9009c2f94d1-HHS-TLennon]  
Kellogg, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cochran, Norris (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Dasher, David (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Cederberg, Christina

CC:

---

(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]

**Subject:** COVID-19 Daily (3/6) Disaster Leadership Group Meeting

**Attachments:** COVID-19 Task Force Structure-DRAFT-20200305v3-CLEAN.docx; COVID-19 SLB 5Mar20 Final.pdf

**Location:** Conference Number: (b)(6) Access Code: (b)(6) | Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

**Start:** 3/6/2020 3:00:00 PM

**End:** 3/6/2020 4:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

**Update:** Please see attached the following documents:

- 1) the COVID-19 Task Force Structure
- 2) COVID-19 Senior Leader Brief for March 5, 2020

Additionally, please see the added WebEx link below for today's meeting.

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The second meeting in this series is scheduled for Friday, March 6 from 3:00PM-4:00PM. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

### **Read Ahead Materials**

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

### **Meeting Logistics & Conference Line**

**Conference Number:** (b)(6)

**Meeting Access Code:** (b)(6)

**WebEx Link:** [Start the meeting](#)

These sessions will be held in conference room 624D.7, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. A conference line is provided for those of you unable to join the meeting in person.

If you have any questions, please reach out to me Dan Dodgen ([Daniel.Dodgen@hhs.gov](mailto:Daniel.Dodgen@hhs.gov)) and kindly copy [DLGDESK@hhs.gov](mailto:DLGDESK@hhs.gov).

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC  
20515

o: **(b)(6)**

[Daniel.Dodgen@HHS.Gov](mailto:Daniel.Dodgen@HHS.Gov) | [www.phe.gov](http://www.phe.gov)



---

**From:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]  
**Sent:** 3/6/2020 2:44:14 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS); Fucci, Michael (OS); Donnelly, Kelsey S (OS); Roman-Stolte, Claudia (OS); Stannard, Paula (OS); Mango, Paul (OS); Agnew, Ann (OS); Trueman, Laura (OS); Kadlec, Robert P (OS); Bird, Catherine (OS); Hittle, Taylor (OS); Arbes, Sarah C (OS); Bradsher, Kris (OS); Murphy, Ryan (OS); Destro, Brenda (OS); Nevel, Amy (OS); Tobias, Constance (OS); Giroir, Brett (OS); Schwartz, Erica (OS); Severino, Roger (OS); Bell, March (OS); Frohboese, Robinsue (OS); Grigsby, Garrett G (OS); Kerr, Lawrence (OS); Chang, William (OS); Taitsman, Julie (OIG); Griswold, Nancy J (OS); McDaniel, Eileen C (OS); Rucker, Donald (OS); Chaput, Daniel (OS); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine M (ACL); Meyers, David (AHRQ); McNellis, Robert (AHRQ); Patel, Anita (CDC); Ethier, Kathleen A (CDC); Knutson, Donna B (CDC); Brookes, Brady (CMS); Payne, Skip (CMS); Blackford, Carol W (CMS); Hahn, Stephen; Hinton, Denise; Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS); McCollum, Jeffrey (IHS); Frazier, Francis (IHS); Collins, Francis S (NIH); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); McCance-Katz, Elinore (SAMHSA); Delvecchio, Paolo (SAMHSA); Lobos, Elisa (SAMHSA); Shuy, Bryan (OS); Yeskey, Kevin (OS); Bright, Rick (OS); Disbrow, Gary (OS); Lambert, Linda (OS); Phillips, Sally (OS); Mark.g.hartell.mil@mail.mil; Smith, Matthew (OS); Greene, Jonathan (OS); Cooper, Kevin (OS); Imbriale, Samuel (OS); DeBord, Kristin (OS); Gin, Julia (OS); Adams, Steven A (CDC); Lee, Scott (OS); Austin, Meredith (uscg.mil); Wolf, Laura K (OS); Perdue, Christopher (OS); Herrmann, John (OS); Johnson, Robert (OS); Wong, Diana (OS); Vineyard, Michael (OS); Mackay, Thomas F (OS); Moudy, Robin (OS); Dodgen, Daniel (OS); Gettinger, Andrew (OS); Abbey, Rachel (OS); Lennon, Todd (HRSA); Kellogg, Rachel (OS); Bettencourt, Alice (OS); Cochran, Norris (OS); Dasher, David (OS); Cederberg, Christina (OS); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Lawrence, Theresa (OS)

**Subject:** COVID-19 Daily (3/6) Disaster Leadership Group Meeting  
**Attachments:** COVID-19 Task Force Structure-DRAFT-20200305v3-CLEAN.docx; COVID-19 SLB 5Mar20 Final.pdf; COVID-19-DLG-Agenda-03-06-2020 FINAL.docx  
**Location:** Conference Number: (b)(6), Access Code: (b)(6) Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201  
**Start:** 3/6/2020 3:00:00 PM  
**End:** 3/6/2020 4:00:00 PM  
**Show Time As:** Tentative

Update: Please see attached the following documents:

- 1) the COVID-19 Task Force Structure
- 2) COVID-19 Senior Leader Brief for March 5, 2020
- 3) Final Agenda for Today's Meeting

Additionally, please see the added WebEx link below for today's meeting.

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The second meeting in this series is scheduled for Friday, March 6 from 3:00PM-4:00PM. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

### **Read Ahead Materials**

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

### **Meeting Logistics & Conference Line**

Conference Number: (202) (b)(6)

Meeting Access Code: (b)(6)

WebEx Link: [Start the meeting](#)

These sessions will be held in conference room 624D.7, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. A conference line is provided for those of you unable to join the meeting in person.

If you have any questions, please reach out to me Dan Dodgen ([Daniel.Dodgen@hhs.gov](mailto:Daniel.Dodgen@hhs.gov)) and kindly copy [DLGDESK@hhs.gov](mailto:DLGDESK@hhs.gov).

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC  
20515

o. (202) (b)(6)

[Daniel.Dodgen@HHS.Gov](mailto:Daniel.Dodgen@HHS.Gov) | [www.phe.gov](http://www.phe.gov)

**From:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]  
**Sent:** 3/6/2020 2:45:00 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Chaput, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6aee5b76fbac46349df3dbedb2e77511-HHS-Daniel.]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Nicholls, Richard (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baae1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86ebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Ethier, Kathleen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7895b283237401cb312576b43fef452-HHS-kbe0-cd]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Macrae, Jim (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2b83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8f8e2f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Mark.g.hartell.mil@mail.mil; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Dodgen, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Gettinger, Andrew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=17c5a2d5b6284d2ca58f9de61500f3fe-HHS-Andrew.]; Abbey, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e829e079e04eb48bdb70b832423c8f-HHS-Rachel.]; Lennon, Todd (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=96a7c26cba7943b2b2f9c9009c2f94d1-HHS-TLennon]; Kello, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Dasher, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

CC:

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Cederberg, Christina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]

**Subject:** COVID-19 Daily (3/6) Disaster Leadership Group Meeting

**Attachments:** COVID-19 Task Force Structure-DRAFT-20200305v3-CLEAN.docx; COVID-19 SLB 5Mar20 Final.pdf; COVID-19-DLG-Agenda-03-06-2020 FINAL.docx

**Location:** Conference Number: (b)(6) Access Code: (b)(6) | Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

**Start:** 3/6/2020 3:00:00 PM

**End:** 3/6/2020 4:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

Update: Please see attached the following documents:

- 1) the COVID-19 Task Force Structure
- 2) COVID-19 Senior Leader Brief for March 5, 2020
- 3) Final Agenda for Today's Meeting

Additionally, please see the added WebEx link below for today's meeting.

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The second meeting in this series is scheduled for Friday, March 6 from 3:00PM-4:00PM. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

### **Read Ahead Materials**

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

### **Meeting Logistics & Conference Line**

**Conference Number:** (202) (b)(6)

**Meeting Access Code:** (b)(6)

**WebEx Link:** [Start the meeting](#)

These sessions will be held in conference room 624D.7, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. A conference line is provided for those of you unable to join the meeting in person.

If you have any questions, please reach out to me Dan Dodgen ([Daniel.Dodgen@hhs.gov](mailto:Daniel.Dodgen@hhs.gov)) and kindly copy [DLGDESK@hhs.gov](mailto:DLGDESK@hhs.gov).

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC

20515

o. (202) (b)(6)

[Daniel.Dodgen@HHS.Gov](mailto:Daniel.Dodgen@HHS.Gov) | [www.phe.gov](http://www.phe.gov)

---

**From:** Ford, Robert B [Robert.Ford@abbott.com]  
**Sent:** 3/6/2020 5:27:42 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]  
**Subject:** Quick Follow-up

Dr. Hahn,

It was a pleasure speaking to you at the roundtable with Vice President Pence on diagnostic testing for coronavirus. Abbott is committed to help bring diagnostic tests to the American people with the speed and scale necessary to combat this challenge. (b)(4)

(b)(4) he second, a point of care test which we discussed briefly, is in most physician offices and can be used at convenient locations for patients with rapid results.

I just wanted to make sure I reached out to you and gave you an update.

We have already begun discussions with your team and they have moved very fast to assist us. We are ready to partner with the FDA to bring more testing a capacity. When Secretary Azar posed the question regarding South Korea testing capability vs. the US, I didn't have a chance to add commentary, but I believe there are some insights that we could incorporate, that could get us there.

It was good to meet you and look forward to staying in touch.

Robert B. Ford  
Abbott Laboratories

(b)(6)



**From:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]  
**Sent:** 3/6/2020 5:36:44 PM  
**To:** Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Chaput, Daniel (OS)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6aee5b76fbac46349df3dbedb2e77511-HHS-Daniel.]; Johnson, Lynn (ACF)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Nicholls, Richard (ACL)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baae1-HHS-Richard]; Phillips, Christine M  
 (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86ebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert  
 (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Ethier, Kathleen A  
 (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7895b283237401cb312576b43fef452-HHS-kbe0-cd]; Knutson, Donna B  
 (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Brookes, Brady (CMS)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Blackford, Carol W  
 (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Hahn, Stephen  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana  
 (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Macrae, Jim (HRSA)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael  
 (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey  
 (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2b2f83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore  
 (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo  
 (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Mark.g.hartell.mil@mail.mil; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Dodgen, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Gettinger, Andrew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=17c5a2d5b6284d2ca58f9de61500f3fe-HHS-Andrew.]; Abbey, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e829e079e04eb48bdb70b832423c8f-HHS-Rachel.]; Lennon, Todd (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=96a7c26cba7943b2b2f9c9009c2f94d1-HHS-TLennon]; Dasher, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]

CC: Kellogg, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cederberg, Christina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Seiler, Brittney J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bec759d8a37149dd9a94b730ff725a9b-HHS-Brittne]; DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]

**Subject:** Distribution: Summary of Conclusions - COVID-19 Daily (3/6) Disaster Leadership Group Meeting

**Attachments:** COVID-19-DLG-Summary of Conclusions-03-06-2020.docx

Dear Disaster Leadership Group (DLG) Members,

This email serves to transmit the attached Summary of Issues prepared for the COVID-19 DLG convened on March 6, 2020. We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message.

Please forward any questions or concerns related to this document to me, the DLG Policy Lead for this forum at [Daniel.Dodgen@hhs.gov](mailto:Daniel.Dodgen@hhs.gov) and kindly cc: [DLGDESK@hhs.gov](mailto:DLGDESK@hhs.gov) on any communications.

Thank you,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) (b)(6)

[Daniel.Dodgen@HHS.Gov](mailto:Daniel.Dodgen@HHS.Gov) | [www.phe.gov](http://www.phe.gov)

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 3/6/2020 6:33:48 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** (b)(5)

Please review the draft note and once you clear I will send out on your behalf. Thank you. (Nice job at the presser!)

(b)(5)

Sincerely,

Stephen M. Hahn, M.D.  
FDA Commissioner

---

**From:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Date:** March 6, 2020 at 6:46:25 AM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>  
**Subject:** Fwd: Quest intends to launch Monday 3/9

Need a thank you email to them.

Thanks

S

Sent from my iPad

Begin forwarded message:

**From:** "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>  
**Date:** March 5, 2020 at 8:02:30 PM EST  
**To:** "Schwartz, Suzanne" <Suzanne.Schwartz@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Stenzel, Timothy" <Timothy.Stenzel@fda.hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Subject:** Re: Quest intends to launch Monday 3/9

Amen to that. We are indeed very lucky.

Jeff

---

**From:** Schwartz, Suzanne <[Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)>  
**Date:** March 5, 2020 at 8:00:02 PM EST  
**To:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)>, Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>  
**Cc:** Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>  
**Subject:** Re: Quest intends to launch Monday 3/9

It's times like these that bring to light how blessed we are to have such dedicated, passionate and outstanding individuals committed to our mission....truly invaluable assets to our organization and to the American public. We ask a lot of them and they give even more...  
Suzanne

Suzanne B. Schwartz, MD, MBA  
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)  
Center for Devices & Radiological Health  
US Food & Drug Administration  
Office: 301-796-6937  
Mobile: 202-841-9996

---

**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>  
**Date:** March 5, 2020 at 7:42:33 PM EST  
**To:** Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)>, Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>  
**Cc:** Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>, Schwartz, Suzanne <[Suzanne.Schwartz@fda.hhs.gov](mailto:Suzanne.Schwartz@fda.hhs.gov)>  
**Subject:** Re: Quest intends to launch Monday 3/9

Adding the Commissioner. You all have really gone above and beyond. Very impressive.

Sent from my iPhone

On Mar 5, 2020, at 6:36 PM, Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)> wrote:

Hi Keagan,

Kind words from Quest.

Best,

*Tim*

**Timothy T. Stenzel, MD, PhD**  
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health  
Office of Product Evaluation and Quality*

Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)

**Jennifer Campbell**  
Administrative Assistant

OHT7: Office of *In Vitro* Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration  
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993  
Ph: 301-796-7692  
[Jennifer.Campbell@fda.hhs.gov](mailto:Jennifer.Campbell@fda.hhs.gov)

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:  
<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

---

**From:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>  
**Sent:** Thursday, March 5, 2020 6:32 PM  
**To:** Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)>; Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>  
**Cc:** St. Pierre, Don J. <[don.st.pierre@fda.hhs.gov](mailto:don.st.pierre@fda.hhs.gov)>  
**Subject:** RE: Quest intends to launch Monday 3/9

Thank you.

You have a great team.

Quest really appreciates FDA's support and understanding.

And Quest appreciates all the late night hours and weekend hours put in by your team.

Michael

Michael J. Wagner, Esq.  
Quest Diagnostics Incorporated | Legal Department | 1311 Calle Batido | San Clemente, CA 92673 USA | phone +1 949.940.7360 | [michael.j.wagner@questdiagnostics.com](mailto:michael.j.wagner@questdiagnostics.com) | [www.questdiagnostics.com](http://www.questdiagnostics.com)  
Please think about resource conservation before you print this message

---

**From:** Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)>  
**Sent:** Thursday, March 5, 2020 1:57 PM  
**To:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>; Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>  
**Cc:** St. Pierre, Don J. <[don.st.pierre@fda.hhs.gov](mailto:don.st.pierre@fda.hhs.gov)>  
**Subject:** RE: Quest intends to launch Monday 3/9

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thanks Michael! Let us know if we can assist in any way.

Best,  
*Tim*

**Timothy T. Stenzel, MD, PhD**  
Director, OHT7: Office of *In Vitro* Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)

**Jennifer Campbell**  
*Administrative Assistant*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration  
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993  
Ph: 301-796-7692  
[Jennifer.Campbell@fda.hhs.gov](mailto:Jennifer.Campbell@fda.hhs.gov)

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:  
<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

---

**From:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>  
**Sent:** Thursday, March 5, 2020 4:51 PM  
**To:** Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>  
**Cc:** St. Pierre, Don J. <[don.st.pierre@fda.hhs.gov](mailto:don.st.pierre@fda.hhs.gov)>; Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)>  
**Subject:** Quest intends to launch Monday 3/9

Quest intends to have the validation complete and start offering the test on Monday 3/9.

Michael

Michael J. Wagner, Esq.  
Quest Diagnostics Incorporated | Legal Department | 1311 Calle Batido | San Clemente, CA 92673 USA | phone +1 949.940.7360 | [michael.j.wagner@questdiagnostics.com](mailto:michael.j.wagner@questdiagnostics.com) | [www.questdiagnostics.com](http://www.questdiagnostics.com)  
Please think about resource conservation before you print this message

---

**From:** Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>  
**Sent:** Thursday, March 5, 2020 1:44 PM  
**To:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>  
**Cc:** St. Pierre, Don J. <[don.st.pierre@fda.hhs.gov](mailto:don.st.pierre@fda.hhs.gov)>; Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>; Stenzel, Timothy <[Timothy.Stenzel@fda.hhs.gov](mailto:Timothy.Stenzel@fda.hhs.gov)>  
**Subject:** RE: and I was impressed with Tremyl  
**Importance:** High

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Michael,

Just of follow up, can you please let me know when you plan to testing sample with your device.

Thanks,

Uwe

**Uwe Scherf, M.Sc., Ph.D.**  
*Director, Division of Microbiology Devices*

OHT7: Office of *In Vitro* Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration  
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993  
Ph: 301-796-5456



[uwe.scherf@fda.hhs.gov](mailto:uwe.scherf@fda.hhs.gov)

**Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:**

<https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E>

---

**From:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>

**Sent:** Wednesday, March 4, 2020 2:46 PM

**To:** Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>

**Cc:** St. Pierre, Don J. <[don.st.pierre@fda.hhs.gov](mailto:don.st.pierre@fda.hhs.gov)>

**Subject:** RE: and I was impressed with Tremyl

Yes sir.

Absolutely.

Michael

Michael J. Wagner, Esq.

Quest Diagnostics Incorporated | Legal Department | 1311 Calle Batido | San Clemente, CA 92673 USA | phone +1 949.940.7360 | [michael.j.wagner@questdiagnostics.com](mailto:michael.j.wagner@questdiagnostics.com) | [www.questdiagnostics.com](http://www.questdiagnostics.com)

Please think about resource conservation before you print this message

---

**From:** Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>

**Sent:** Wednesday, March 4, 2020 11:36 AM

**To:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>

**Cc:** Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>; St. Pierre, Don J. <[don.st.pierre@fda.hhs.gov](mailto:don.st.pierre@fda.hhs.gov)>

**Subject:** FW: and I was impressed with Tremyl

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Michael,

Thank you for your voice mail. Can you please clarify the following issue:

Does Quest plan on notifying FDA through the new policy email when you have completed your validation and are beginning testing?

Thanks, Uwe

**Uwe Scherf, M.Sc., Ph.D.**

Director, Division of Microbiology Devices

OHT7: Office of *In Vitro* Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration  
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993  
Ph: 301-796-5456

[uwe.scherf@fda.hhs.gov](mailto:uwe.scherf@fda.hhs.gov)

**Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:**

<https://www.research.net/s/cdrhcustomerservice?ID=1930&S=E>

---

**From:** Wagner, Michael J <[Michael.J.Wagner@questdiagnostics.com](mailto:Michael.J.Wagner@questdiagnostics.com)>  
**Sent:** Monday, March 2, 2020 2:16 PM  
**To:** Scherf, Uwe <[Uwe.Scherf@fda.hhs.gov](mailto:Uwe.Scherf@fda.hhs.gov)>  
**Subject:** and I was impressed with Tremyl

Tremyl was very welcoming when I called.

She has great presence.

Michael

Michael J. Wagner, Esq.

Quest Diagnostics Incorporated | Legal Department | 1311 Calle Batido | San Clemente, CA 92673 USA | phone +1 949.940.7360 | [michael.j.wagner@questdiagnostics.com](mailto:michael.j.wagner@questdiagnostics.com) | [www.questdiagnostics.com](http://www.questdiagnostics.com)  
Please think about resource conservation before you print this message

---

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

---

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

---

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

---

The contents of this message, together with any attachments, are intended only for the use of the person(s) to which they are addressed and may contain confidential and/or privileged information. Further, any medical information herein is confidential and protected by law. It is unlawful for unauthorized persons to use, review, copy, disclose, or disseminate confidential medical information. If you are not the intended recipient, immediately advise the sender and delete this message and any attachments. Any distribution, or copying of this message, or any attachment, is prohibited.

---

**From:** Elvander, Erika (OS/OGA) [Erika.Elvander@hhs.gov]  
**Sent:** 3/7/2020 10:13:30 AM  
**To:** Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]  
**CC:** Marston, Barbara J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ae062e3e071488a9be7489fa12e5aa5-HHS-bxm5-cd]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d509580ef6419b926735f53a2fc3ae-HHS-Keagan.]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]  
**Subject:** Fwd: 【外部メール】 Re: Conference call between Sec. Azar and Min. Kato Memo for the call  
**Attachments:** DP\_ENVIRO\_20200307\_厚労省\_s.docx; ATT00001.htm

Dear colleagues-

Per the call this morning between Secretary Azar and Minister Kato, please find attached please find **“Environmental sampling for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during a coronavirus disease (COVID-19) outbreak aboard a commercial cruise ship: Preliminary Report”**. We will follow up with them to schedule a working level call. Please let Garrett and I know who from your team you would like to be part of that call.

Thanks so much for your kind attention to this on a Saturday.

Cheers,

Erika

---

Erika Elvander  
Director, Asia and the Pacific  
Office of Global Affairs, HHS  
Sent from my iPhone

Begin forwarded message

**From:** 喜多 洋輔(kita-yousuke) <kita-yousuke@mhlw.go.jp>

**Sent:** Saturday, March 7, 2020 9:12 AM

**To:** Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>; Tignor, Beth (HHS/IOS) <Beth.Tignor@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Koo, Han (OS/OGA) (CTR) <Han.Koo@hhs.gov>; Callaghan-Arguelles, Christine (HHS/IOS) <Christine.Callaghan-arguelles@hhs.gov>

**Cc:** YOSHIDA TAKUNO <takuno.yoshida@mofa.go.jp>; 横堀 雄太(yokobori-yuuta.mi5) <yokobori-yuuta.mi5@mhlw.go.jp>; 松村 漢志(matsumura-hiroshi) <matsumura-hiroshi@mhlw.go.jp>; 堀内 日佐世(horiuchi-hisayo.ho8) <horiuchi-hisayo.ho8@mhlw.go.jp>; 野口 千彰(noguchi-chiaki.05y) <noguchi-chiaki.05y@mhlw.go.jp>; 乃村 久代(nomura-hisayo) <nomura-hisayo@mhlw.go.jp>; 佐原 康之(sahara-yasuyuki) <sahara-yasuyuki@mhlw.go.jp>; 平岩 勝(hiraiwa-masaru) <hiraiwa-masaru@mhlw.go.jp>; 田口 一穂(taguchi-kazuho.is5) <taguchi-kazuho.is5@mhlw.go.jp>

**Subject:** RE: 【外部メール】 Re: Conference call between Sec. Azar and Min. Kato Memo for the call

Dear Erika and US HHS colleagues

We appreciate you for today's ministerial call. As our minister mentioned in the call, we would be very happy to have working level conference call, especially for the Grand Princess incident, if necessary.

Finally, please find the attached preliminary paper on the Diamond Princess environmental sampling results for your reference, in which

you can see survival rates of SARS-CoV-2 virus on the surface, pillows and so on. Really interesting results.

We believe this would also help you to find the way to cope with the Cruise ship.

Best wishes

**KITA Yosuke** MD MPH MPA

Senior Coordinator for Global Health

Ministry of Health Labor and Welfare of Japan

E-mail: [kita-yousuke@mhlw.go.jp](mailto:kita-yousuke@mhlw.go.jp)

(b)(6)

Fax: +81 33 502 6678

1-2-2 Kasumigaseki Chiyoda Tokyo

100-8916 Japan

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 3/7/2020 3:24:50 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Fwd: Gilead Statement  
**Attachments:** 20.03.07\_Gilead Remdesivir Statement.pdf; ATT00001.htm

Gilead statement

Sent from my iPhone

Begin forwarded message:

**From:** "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>  
**Date:** March 7, 2020 at 3:15:39 PM EST  
**To:** "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "McKeogh, Katherine (OS)" <Katherine.McKeogh@hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "Harrison, Brian (OS)" <Brian.Harrison@hhs.gov>, "Charrow, Robert (OS)" <Robert.Charrow@hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: Gilead Statement

FYI

---

**From:** Brett Pletcher <Brett.Pletcher@gilead.com>  
**Date:** March 7, 2020 at 3:08:25 PM EST  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Subject:** Gilead Statement

Hi Stacy,

As a follow-up to my earlier message, I have attached Gilead's statement to Axios in response to their questions. The statement will also be made available to others.

Brett

Brett Pletcher  
EVP, Corporate Affairs, General Counsel and Corporate Secretary  
Gilead Sciences | Office: 1 (650) 522 6219

NOTICE: This e-mail and all attachments transmitted with it are intended solely for the use of the addressees and may contain legally privileged, protected or confidential information. If you have received this message in error, please notify the sender immediately by e-mail reply and please delete this e-mail message from your computer and destroy any copies.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/8/2020 12:55:37 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Fwd: updated Q and A  
**Attachments:** FY 2021 Master Hot Topic Q-A - FINAL- MM.docx

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Date:** March 7, 2020 at 2:52:23 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** RE: updated Q and A

Hi—

And, attached now is a finalized Q and A doc. I added in all the additional info you requested. However, we will need to get you updated Coronavirus numbers/info on Monday.

Also, just a reminder that your hearing binder has lots of info too if you need a quick reference and it also has top line messages on every paper.

Thanks and let me know what else you need.

---

**From:** McBride, Maren  
**Sent:** Saturday, March 7, 2020 11:30 AM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** RE: updated Q and A

Also, attached is an updated version of the oral testimony. We incorporated your edits. I included a marked up version so you could see where we made edits. There is also a clean version attached that is easier to read.

If you have time, you may want to practice how long it takes you. You will only have 5 minutes for your opening so we may need to cut depending on your delivery style. When I read it, it's over 5 minutes.

---

**From:** McBride, Maren  
**Sent:** Friday, March 6, 2020 6:09 PM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** updated Q and A

Commissioner—

Attached is an updated Q and A doc based on our conversation earlier. You will notice there are a few areas that are highlighted. Those are questions I still need to update based on additional info you requested. I should have those done by tomorrow morning but I didn't want to hold up your review of all the other questions in the meantime.

I will also have your updated oral testimony for you tomorrow too.

Let me know if you have any questions-I'm around all weekend. Thanks.

**From:** Droegemeier, Kelvin K. EOP/OSTP (b)(6)  
**Sent:** 3/8/2020 9:48:47 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Pottinger, Matthew F. EOP/WHO (b)(6); Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kratsios, Michael J. EOP/OSTP (b)(6); Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Campana, Alexandra D. EOP/WHO (b)(6); Caro Rivera, Juan A. EOP/WHO (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Waterman, Paige E. EOP/OSTP (b)(6)  
**Subject:** Re: Devices for surface testing

NIST has some protocols too.

On Mar 8, 2020, at 9:27 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thanks, Joe. Preliminary read but happy to have a conversation.

(b)(5)

Steve

---

**From:** Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>  
**Date:** March 7, 2020 at 8:20:04 PM EST  
**To:** Droegemeier, Kelvin K. EOP/OSTP <Kelvin.K.Droegemeier@ostp.eop.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Redfield, Robert R (CDC) <olx1@cdc.gov>, McGowan, Robert K (CDC) <omc2@cdc.gov>, Pottinger, Matthew F. EOP/WHO (b)(6); Shah, Anand <Anand.Shah@fda.hhs.gov>, Kratsios, Michael J. EOP/OSTP (b)(6); Bonner, Maria K. EOP/WHO <Maria.K.Bonner@who.eop.gov>, Campana, Alexandra D. EOP/WHO (b)(6); Caro Rivera, Juan A. EOP/WHO (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Waterman, Paige E. EOP/OSTP (b)(6)  
**Subject:** Re: Devices for surface testing



With Steve Hahn from FDA

Sent from my iPhone

> On Mar 7, 2020, at 8:17 PM, Droegemeier, Kelvin K. EOP/OSTP <(b)(6)> wrote:

>

> I'm copying Ian and Paige at OSTP to get their thoughts

(b)(5)

>

> Kelvin

>

>

>> On Mar 7, 2020, at 8:08 PM, Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov> wrote:

>>

(b)(5)

>> Joe

>>

>> Sent from my iPhone

---

**From:** Giroir, Brett (HHS/OASH) [Brett.Giroir@hhs.gov]  
**Sent:** 3/10/2020 7:14:36 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** FW: info on what needs to be ordered - i will check on the backlog

Can you give me a call?  
Re kits and extraction, and all that is testing

(b)(6)

**Brett P. Giroir, MD**  
ADM, US Public Health Service  
Assistant Secretary for Health (ASH)  
200 Independence Avenue, SW  
Washington, DC 20201  
Office Phone: 202-690-7694

---

**From:** Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>  
**Sent:** Tuesday, March 10, 2020 7:13 PM  
**To:** Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>  
**Cc:** Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>  
**Subject:** Fwd: info on what needs to be ordered - i will check on the backlog

Sherri is getting you the name for lab issue. Below has follow up I shared w CA Health Secretary about cause of shortage and some of the options being worked. I also sent something to Debbi Birx when she asked and will find that message

Get [Outlook for iOS](#)

---

**From:** Schuchat, Anne MD (CDC/OD)  
**Sent:** Tuesday, March 10, 2020 10:55:41 AM  
**To:** Ghaly, Mark (CHHS) <Mark.Ghaly@chhs.ca.gov>  
**Subject:** RE: info on what needs to be ordered - i will check on the backlog

Not sure which you mean. If you mean tht graph of daily tests run by cdc and by public health labs it is here  
<https://www.cdc.gov/coronavirus/2019-ncov/testing-in-us.html>

(page down to see the graph – it is after the map of what states are testing vs. in progress of getting test validated).  
Re the backlog – here is the summary:

National shortage of the quiagen extraction components – request to Qiagen to send letter to cdc about comparability of their research use only products vs. good manufacturing products as a means to let us get FDA to permit those products being shipped out to fill the gap. We have not gotten that letter so this is in that company’s hands.  
Labs could try to use a different platform (eg the magnapure made by roche) which does not rely on those Qiagen products. Some places are pursuing that route. I don’t have info yet if any of the CA Counties are close to being able to do that.

Commercial testing is starting to get moved out by Lab corps and soon by quest – this is private sector and not run out of CDC.

---

**From:** Ghaly, Mark (CHHS) <[Mark.Ghaly@chhs.ca.gov](mailto:Mark.Ghaly@chhs.ca.gov)>

**Sent:** Tuesday, March 10, 2020 10:42 AM

**To:** Schuchat, Anne MD (CDC/OD) <[acs1@cdc.gov](mailto:acs1@cdc.gov)>

**Subject:** Re: info on what needs to be ordered - i will check on the backlog

Hi, can you please send me the link to your testing diagram? Ty

Also, any news on backlog.

Sent from my iPhone

On Mar 10, 2020, at 6:31 AM, Schuchat, Anne MD (CDC/OD) <[acs1@cdc.gov](mailto:acs1@cdc.gov)> wrote:

Anne Schuchat, MD  
Principal Deputy Director  
Centers for Disease Control and Prevention  
Rear Admiral, US Public Health Service (Retired)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/11/2020 8:55:38 AM  
**To:** Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]  
**Subject:** Fwd: For Today's Hearing  
**Attachments:** COVID-19 FDA role in Dx for emergency.docx; FDA role in Dx for emergency\_ss.docx

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Date:** March 11, 2020 at 6:45:17 AM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** For Today's Hearing

You may find two attachments helpful for today's hearing. The first summarizes our efforts around test development and availability. The second summarizes some of our efforts to address possible test supply shortages. (b)(5)

(b)(5)

(b)(5)

I will provide some additional information in a separate email.

---

**From:** McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]  
**Sent:** 3/11/2020 10:28:12 AM  
**To:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** RE: time sensitive -- call with senator murray this morning

Below is article FSA

## ***‘It’s Just Everywhere Already’: How Delays in Testing Set Back the U.S. Coronavirus Response***

A series of missed chances by the federal government to ensure more widespread testing came during the early days of the outbreak, when containment would have been easier.



A research project in Seattle tried to conduct early tests for the new coronavirus but ran into red tape before circumventing federal officials and confirming a case. Credit...Grant Hindsley for The New York Times

**By Sheri Fink and Mike Baker**

• Published March 10, 2020 Updated March 11, 2020, 10:04 a.m. ET

Dr. Helen Y. Chu, an infectious disease expert in Seattle, knew that the United States did not have much time.

In late January, the first confirmed American case of the [coronavirus](#) had landed in her area. Critical questions needed answers: Had the man infected anyone else? Was the deadly virus already lurking in other communities and spreading?

As luck would have it, Dr. Chu had a way to monitor the region. For months, as part of a research project into the flu, she and a team of researchers had been collecting nasal swabs from residents experiencing symptoms throughout the Puget Sound region.

To repurpose the tests for monitoring the coronavirus, they would need the support of state and federal officials. But nearly everywhere Dr. Chu turned, officials repeatedly rejected the idea, interviews and emails show, even as weeks crawled by and outbreaks emerged in countries outside of China, where the infection began.

By Feb. 25, Dr. Chu and her colleagues could not bear to wait any longer. They began performing coronavirus tests, without government approval.

What came back confirmed their worst fear. They quickly had a positive test from a local teenager with no recent travel history. The coronavirus had already established itself on American soil without anybody realizing it.

“It must have been here this entire time,” Dr. Chu recalled thinking with dread. “It’s just everywhere already.”

In fact, officials would later discover through testing, the virus had already contributed to the deaths of two people, and it would go on to kill 20 more in the Seattle region over the following days.

Federal and state officials said the flu study could not be repurposed because it did not have explicit permission from research subjects; the labs were also not certified for clinical work. While acknowledging the ethical questions, Dr. Chu and others argued there should be more flexibility in an emergency during which so many lives could be lost. On Monday night, state regulators told them to stop testing altogether.

The failure to tap into the flu study, detailed here for the first time, was just one in a series of missed chances by the federal government to ensure more widespread testing during the early days of the outbreak, when

containment would have been easier. Instead, local officials across the country were left to work in the dark as the crisis grew undetected and exponentially.

Even now, after weeks of mounting frustration toward federal agencies over flawed test kits and burdensome rules, states with growing cases such as New York and California are struggling to test widely for the coronavirus. The continued delays have made it impossible for officials to get a true picture of the scale of the growing outbreak, which has now spread to at least 36 states and Washington, D.C.

Dr. Robert R. Redfield, director of the Centers for Disease Control and Prevention, said in an interview on Friday that acting quickly was critical for combating an outbreak. “Time matters,” he said. He insisted that despite the rocky start, there was still time to beat back the coronavirus in the United States. “It’s going to take rigorous, aggressive public health — what I like to say, block and tackle, block and tackle, block and tackle,” he said. “That means if you find a new case, you isolate it.”

Get an informed guide to the global outbreak with our daily coronavirus newsletter.

But the Seattle Flu Study illustrates how existing regulations and red tape — sometimes designed to protect privacy and health — have impeded the rapid rollout of testing nationally, while other countries ramped up much earlier and faster. Faced with a public health emergency on a scale potentially not seen in a century, the United States has not responded nimbly.

The C.D.C.’s own effort to create a system for monitoring the virus around the country, using established government surveillance networks for the flu, has not yet built steam. And as late as last week, after expanding authorizations for commercial and academic institutions to make tests, administration officials provided conflicting accounts of when a significant increase in tests would be available.

In states like Maine, Missouri and Michigan, where there are few or no known infections, state public health officials say they have more than enough tests to meet demand.

But it remains unclear how many Americans have been tested for the coronavirus. The C.D.C. says approximately 8,500 specimens or nose swabs have been taken since the beginning of the outbreak — a figure that is almost certainly larger than the number of people tested since one person can have multiple swabs. By comparison, South Korea, which discovered its first case around the same time as the United States, has reported having the capacity to test roughly 10,000 people a day since late February.

## A prime mission

As soon as the genetic sequence of the coronavirus was published in January, the C.D.C.’s first job was to develop a diagnostic test. “That’s our prime mission,” Dr. Redfield said, “to get eyes on this thing.”

The agency also released criteria for deciding which individuals should be tested for the virus — at first only those who had a fever and respiratory issues and had traveled from the outbreak’s origin in Wuhan, China.

The criteria were so strict that the sick man in the Seattle area who had visited Wuhan did not meet it. Still, worried state health officials pushed to get him checked, and the C.D.C. agreed. Local officials sent a sample to Atlanta and the results came back positive.

Officials monitored 70 people who were in contact with the man, including 50 who consented to getting nose swabs, and none tested positive for the coronavirus. But there was still the possibility that someone had been missed, said Dr. Scott Lindquist, the state epidemiologist for communicable diseases.

Around this time, the Washington State Department of Health began discussions with the Seattle Flu Study already going on in the state.

But there was a hitch: The flu project primarily used research laboratories, not clinical ones, and its coronavirus test was not approved by the Food and Drug Administration. And so the group was not certified to provide test results to anyone outside of their own investigators. They began discussions with state, C.D.C. and F.D.A. officials to figure out a solution, according to emails and interviews.

Dr. Scott F. Dowell, a former high-ranking C.D.C. official and a current deputy director at the Bill & Melinda Gates Foundation, which funds the Seattle Flu Study, asked for help from the leaders of the C.D.C.’s coronavirus response. “Hoping there is a solution,” he wrote on Feb. 10.

Later, Dr. Lindquist, the state epidemiologist in Washington, wrote an email to Dr. Alicia Fry, the chief of the C.D.C.’s epidemiology and prevention branch, requesting the study be used to test for the coronavirus.

C.D.C. officials repeatedly said it would not be possible. “If you want to use your test as a screening tool, you would have to check with F.D.A.,” Gayle Langley, an officer at the C.D.C.’s National Center for Immunization

and Respiratory Disease, wrote back in an email on Feb. 16. But the F.D.A. could not offer the approval because the lab was not certified as a clinical laboratory under regulations established by the Centers for Medicare & Medicaid Services, a process that could take months.

Dr. Chu and Dr. Lindquist tried repeatedly to wrangle approval to use the Seattle Flu Study. The answers were always no.

“We felt like we were sitting, waiting for the pandemic to emerge,” Dr. Chu said. “We could help. We couldn’t do anything.”

## **Sense of exasperation**

As Washington State debated with the federal officials over what to do, the C.D.C. confronted the daunting task of testing more widely for the coronavirus.

The C.D.C. had designed its own test as it typically does during an outbreak. Several other countries also developed their own tests.

But when the C.D.C. shipped test kits to public labs across the country, some local health officials began reporting that the test was producing invalid results.

The C.D.C. promised that replacement kits would be distributed within days, but the problem stretched on for over two weeks. Only five state laboratories were able to test in that period. Washington and New York were not among them.

By Feb. 24, as new cases of the virus began popping up in the United States, the state labs were growing frantic.

The Association of Public Health Laboratories made what it called an “extraordinary and rare request” of Dr. Stephen Hahn, the commissioner of the F.D.A., asking him to use his discretion to allow state and local public health laboratories to create their own tests for the virus.

“We are now many weeks into the response with still no diagnostic or surveillance test available outside of C.D.C. for the vast majority of our member laboratories,” Scott Becker, the chief executive of the association, wrote in a letter to Dr. Hahn.

Dr. Hahn responded two days later, saying in a letter that “false diagnostic test results can lead to significant adverse public health consequences” and that the laboratories were welcome to submit their own tests for emergency authorization.

But the approval process for laboratory-developed tests was proving onerous. Private and university clinical laboratories, which typically have the latitude to develop their own tests, were frustrated about the speed of the F.D.A. as they prepared applications for emergency approvals from the agency for their coronavirus tests.

Dr. Alex Greninger, an assistant professor at the University of Washington Medical Center in Seattle, said he became exasperated in mid-February as he communicated with the F.D.A. over getting his application ready to begin testing. “This virus is faster than the F.D.A.,” he said, adding that at one point the agency required him to submit materials through the mail in addition to over email.

New tests typically require validation — running the test on known positive samples from a patient or a copy of the virus genome. The F.D.A.’s process called for five. Obtaining such samples has been hard because most hospital labs have not seen coronavirus cases yet, said Dr. Karen Kaul, chair of the department of pathology and laboratory medicine at NorthShore University HealthSystem in Illinois.

She said she had to scramble to obtain virus RNA from a laboratory in Europe. “Everyone is trying to figure out what we can get to help us gather the data that we need,” she said.

The F.D.A. has disputed that it moved too slowly, saying that it provided emergency authorization for two laboratory-developed tests within 24 hours of a completed submission — one was the C.D.C.’s test and the other a test developed by New York’s Wadsworth laboratory after it had trouble verifying the C.D.C.’s test.

## **‘What do we do?’**

On the other side of the country in Seattle, Dr. Chu and her flu study colleagues, unwilling to wait any longer, decided to begin running samples.

A technician in the laboratory of Dr. Lea Starita who was testing samples soon got a hit.

“I’m like, ‘Oh my God,’” Dr. Starita said. “I just took off running” to the office of the study’s program managers. “We got one,” she told them. “What do we do?”



Members of the research group discussed the ethics of what to do next.

“What we were allowed to do was to keep it to ourselves,” Dr. Chu said. “But what we felt like we needed to do was to tell public health.”

They decided the right thing to do was to inform local health officials.

The case was a teenager, in the same county where the first coronavirus case had surfaced, who had a flu swab just a few days before but had no travel history and no link to any known case.

The state laboratory, finally able to begin testing, confirmed the result the next morning. The teenager, who had recovered from his illness, was located and informed just after he entered his school building. He was sent home and the school was later closed as a precaution.

Later that day, the investigators and Seattle health officials gathered with representatives of the C.D.C. and the F.D.A. to discuss what happened. The message from the federal government was blunt. “What they said on that phone call very clearly was cease and desist to Helen Chu,” Dr. Lindquist remembered. “Stop testing.”

## A silent spread

Still, the troubling finding reshaped how officials understood the outbreak. Seattle Flu Study scientists quickly sequenced the genome of the virus, finding a genetic variation also present in the country’s first coronavirus case.

The implications were unnerving. There was a good chance that the virus had been circulating silently in the community for around six weeks, infecting potentially hundreds of people.

On a phone call the day after the C.D.C. and F.D.A. had told Dr. Chu to stop, officials relented, but only partially, the researchers recalled. They would allow the study’s laboratories to test cases and report the results only in future samples. They would need to use a new consent form that explicitly mentioned that results of the coronavirus tests might be shared with the local health department.

They were not to test the thousands of samples that had already been collected.

The same day, the F.D.A. said it would relax its rules and allow clinical labs to begin using their own coronavirus tests as long as they submitted evidence that they worked to the agency. Under that new policy, according to an agency representative on Tuesday, it had heard from 14 labs, with 10 already beginning patient testing.

On March 2, the Seattle Flu Study’s institutional review board at the University of Washington determined that it would be unethical for the researchers not to test and report the results in a public health emergency, Dr. Starita said. Since then, her laboratory has found and reported numerous additional cases, all of which have been confirmed.

As new samples came in, Dr. Starita’s laboratory also worked their way backward through some older samples that had been sitting in the freezers for weeks, finding cases that date back to at least Feb. 20 — seven days before public health officials had any idea the virus was in the community.

The scientists said they believe that they will find evidence that the virus was infecting people even earlier, and that they could have alerted authorities sooner if they had been allowed to test.

But on Monday night, state regulators, enforcing Medicare rules, stepped in and again told them to stop until they could finish getting certified as a clinical laboratory, a process that could take many weeks.

In the days since the teenager’s test, the Seattle region has spun into crisis, with dozens of people testing positive and at least 22 dying — many of them infected in a nursing home that had unknowingly been suffering casualties since Feb. 19.

The availability of testing for coronavirus remains uneven, with some people able to easily obtain tests in certain parts of the country while others have been turned away. Some state officials fear that the virus is spreading far faster than the capacity for testing is increasing.

Looking back, Dr. Chu said she understood why the regulations that stymied the flu study’s efforts for weeks existed. “Those protections are in place for a reason,” she said. “You want to protect human subjects. You want to do things in an ethical way.”

The frustration, she said, was how long it took to cut through red tape to try to save lives in an outbreak that had the potential to explode in Washington State and spread in many other regions. “I don’t think people knew that back then,” she said. “We know it now.”

Reporting was contributed by Nicholas Bogel-Burroughs, Joseph Goldstein, Sheila Kaplan, Michael D. Shear, Knvul Sheikh, Katie Thomas and Noah Weiland.

---

**From:** Gross, Karas

**Sent:** Wednesday, March 11, 2020 10:23 AM

**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** FW: time sensitive -- call with senator murray this morning

**Importance:** High

See below. I will let HHS coordinate and will of course let them know you are testifying soon, but making sure you're aware.

---

**From:** Bath, Nick (HELP Committee) <Nick\_Bath@help.senate.gov>

**Sent:** Wednesday, March 11, 2020 10:16 AM

**To:** Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Brand, Anstice M (CDC) <atb6@cdc.gov>

**Cc:** Fristedt, Andi (HELP Committee) <Andi\_Fristedt@help.senate.gov>; Letter, Elizabeth (HELP Committee) <Elizabeth\_Letter@help.senate.gov>; Backfield, Katlin McKelvie (HELP Committee) <Katlin\_Backfield@help.senate.gov>; Mahoney, Meghan (Murray) <Meghan\_Mahoney@murray.senate.gov>

**Subject:** time sensitive -- call with senator murray this morning

**Importance:** High

Hello all – Senator Murray would like to get on the phone ASAP with the Secretary, Dr. Redfield and Dr. Hahn to discuss last night's New York Times story about the Seattle Flu Project and testing. The Senator's scheduler, Meghan Mahoney, is copied here. Please advise as to timing. My direct is 202 224 6815 and cell is 202 684 5122

Thanks

Nick Bath  
Health Policy Director  
Sen. Patty Murray  
Senate HELP Committee  
202 224 7675

**From:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]  
**Sent:** 3/11/2020 1:07:02 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe193caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C

(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Chaput, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6aee5b76fbac46349df3dbedb2e77511-HHS-Daniel.]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Nicholls, Richard (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baae1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Ethier, Kathleen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7895b283237401cb312576b43fef452-HHS-kbe0-cd]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Macrae, Jim (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Disbrow, Gary (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Cooper, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Dodgen, Daniel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Gettinger, Andrew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17c5a2d5b6284d2ca58f9de61500f3fe-HHS-Andrew.]; Abbey, Rachel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e829e079e04eb48bdb70b832423c8f-HHS-Rachel.]; Lennon, Todd (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96a7c26cba7943b2b2f9c9009c2f94d1-HHS-TLennon]; Dasher, David (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Kellogg, Rachel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cochran, Norris (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Cederberg, Christina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Thornton, Cody R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a7908b18a64fed92a3ddd40eb4c316-HHS-Diana.H]; Donato, Darrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59880927cd1c4c54898474f90a3cf036-HHS-Darrin.]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Robinson, Shante R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b18b5bd335f44389c02-HHS-Shante.]; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Evenhaugen, Stuart T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=787b151ed5be4791a81368f3e48760cc-HHS-Stuart.]; awang@usaid.gov

**CC:** Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Dowell, Chad (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df88ada0638547b2b09bb34ef4fd6b15-HHS-crd7-cd]

**Subject:** COVID-19 Daily Disaster Leadership Group Meeting

**Attachments:** 2018-Influenza-Guidance.pdf; PPE-Prioritization-Scheme-COVID19-20200311\_v2.docx; COVID-19-DLG-Agenda-03-11-2020-FINAL.docx; COVID-19-DLG-Summary of Conclusions-20200310.docx

**Location:** Conference Number: (b)(6), Access Code: (b)(6) | Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

**Start:** 3/11/2020 3:00:00 PM

**End:** 3/11/2020 4:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

### Update:

Dear all,

We are looking forward to today's discussion on prioritization of PPE. As background, please see the attached CDC guidance on "Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic." This document was cleared by the interagency, most recently in 2018. Please focus on Table 1 on page 9.

Also attached is a draft document for discussion, tailoring that table to COVID-19 and PPE. We look forward to your guidance and input to revise and finalize these recommendations.

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

**Read Ahead Materials**

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

**Meeting Logistics & Conference Line**

Conference Number: (b)(6)

Meeting Access Code: (b)(6)

These sessions will be held in conference room 624D.7, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. A conference line is provided for those of you unable to join the meeting in person.

If you have any questions, please reach out to me Dan Dodgen ([Daniel.Dodgen@hhs.gov](mailto:Daniel.Dodgen@hhs.gov)) and kindly copy [DLGDESK@hhs.gov](mailto:DLGDESK@hhs.gov).

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) (b)(6)

[Daniel.Dodgen@HHS.Gov](mailto:Daniel.Dodgen@HHS.Gov) | [www.phe.gov](http://www.phe.gov)

---

**From:** Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]  
**Sent:** 3/11/2020 5:39:00 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]  
**Subject:** Talking Points for Member Briefings Tomorrow  
**Attachments:** SH Congressional Update 3.12.20.docx

Dr. Hahn- Attached are talking points you might use to open the House (8:00am) and Senate (9:15am) briefings tomorrow morning. I will have paper copies tomorrow.

I will meet you in the FDA suite at HHS at 7:20. I recommend we walk to the CVC, weather permitting. A car will pick up after the 9:15 Senate briefing.

My cell is: (b)(6) if anything comes up.

Thank you.

**Andrew Tantillo**

*Deputy Director*

Office of Legislation

U.S. Food and Drug Administration

O: 301-796-8919

(b)(6)

andrew.tantillo@fda.hhs.gov





---

**From:** Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]  
**Sent:** 3/12/2020 1:32:00 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]  
**CC:** Hodgson, Christopher M. EOP/OVP [Christopher.M.Hodgson@ovp.eop.gov]  
**Subject:** FW: [EXTERNAL] I can't verify this. But worth checking  
**Attachments:** Avenu Coronavirus Rapid Test\_HSRP.pdf; DoN SARS-CoV tests 200305 (1).pdf; Flyer-Wondfo One Step COVID-19 Test.pdf

From Rand Paul's office. FYSA.

---

**From:** Doug Stafford <doug@randpaul.com>  
**Sent:** Thursday, March 12, 2020 11:38 AM  
**To:** Short, Marc T. EOP/OVP <Marc.T.Short@ovp.eop.gov>  
**Subject:** [EXTERNAL] I can't verify this. But worth checking

Offered without comment or direct knowledge if he's serious but worth checking

Begin forwarded message:

**From:** Steven Anderson [REDACTED] (b)(6)  
**Date:** March 11, 2020 at 3:21:15 PM EDT  
**To:** Sergio Gor <sergio.gor@gmail.com>  
**Subject:** **Coronavirus Portable Test Kits**

Hello Sergio!!

Good day!

I hope and trust you and Rand are doing just fine. It has been awhile since

I'm lucky enough to work with the direct world holder of the rights for the distributor of of the easiest and simplest corona virus testing kit in the world. It has just been granted EU approval for sales a week ago, including TUV. We are now starting sales in many Middle Eastern and European countries.

As an American and seeing that these testers are critical NOW, I would like to bring this to yours and Rands attention. Who can we contact with to expedite the testing and get these units to the US immediately. We have 1 million testing units available immediately.

Their minimum order is 100,000 units and are able to supply 1 million units a week. Price is only 34 USD/kit FOB.

My idea is all of the relationships you may have in this field of governments, such as Italy, and other aid agencies that desperately need these tester.

One change to the document I am sending to you is that LCs are no longer used as much people are asking for the product and then paying direct when product is ready to be shipped out. Faster and quicker for everyone.

How can we get America the testing kits that it needs?

Regards,  
Steven

Dr. Steven Anderson  
Honorary Past Chairman - Republicans Overseas - United Arab Emirates  
Republicans Overseas - UAE  
Dubai, United Arab Emirates  
>[www.republicansoverseas-uae.com](http://www.republicansoverseas-uae.com)<  
>[www.facebook.com/](http://www.facebook.com/)<|  
  
>[www.republicansoverseas-uae.com](http://www.republicansoverseas-uae.com)<  
>[www.facebook.com/roemirates](http://www.facebook.com/roemirates)<

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 3/12/2020 5:13:13 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FW: FDA Hotline Information

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Thursday, March 12, 2020 4:59 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** FDA Hotline Information

FDA's Office of Legislation would like to flag that FDA's hotline (1-888-INFO-FDA) is available 24 hours a day for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples. We also encourage labs to reach out at [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov) with any questions related to diagnostic development. We hope this will be useful to your constituent developers.

You may also be interested in our COVID-19 [Frequently Asked Questions](#) page, which contains information on vaccines, diagnostic tests, drugs, medical devices, food and other products FDA regulates.

Thank you and please don't hesitate to contact Lauren Paulos at [lauren.paulos@fda.hhs.gov](mailto:lauren.paulos@fda.hhs.gov) if you have any questions or need information as this situation develops.

---

**From:** Russ, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2900752ACF81445785FB0F5B23C728C8-WRUSS]  
**Sent:** 3/12/2020 7:34:29 PM  
**To:** Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mignone, Alfred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]  
**CC:** O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]; Varnado, Martina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad1d1bc50f7941718b0feeb194cbaff1-Martina.Var]; Sullivan, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae24c9d6cdb7403c9b6cb1e76585d5c1-ASullivan]  
**Subject:** FW: Expand COVID-19 Testing  
**Importance:** High  
**Flag:** Follow up

Hello.

Just want to share the email below for your awareness that came in to the Commissioner's public mailbox. We have received 330 of these emails since 5:30 p.m. OES will be logging as a write-in and keep count.

Thank you,

Wanda Russ  
Supervisory Policy Analyst  
FDA Executive Secretariat/

-----Original Message-----

From: (b) (6) (b) (6)  
Sent: Thursday, March 12, 2020 7:25 PM  
To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
Subject: Expand COVID-19 Testing

(b) (6)

March 12, 2020

Dear Stephen M. Hahn,

Dear President Trump:

I am writing as a member of our nation's laboratory medicine team, which includes pathologists and laboratory professionals, to raise my concerns about America's capacity to meet patient testing needs for COVID-19. To date, other countries are doing a better job addressing the diagnostic needs of their patients.

Our government needs to take assertive action to expand the capacity of our nation's clinical laboratories to provide diagnostic testing for the COVID-19 virus in order to hasten its containment. The United States' clinical laboratories are having difficulties securing the resources needed for COVID-19 testing. Labs need an unfettered supply of test kits, instrumentation, reagents and DNA extraction kits, as well as the virus samples necessary to accurately and reliably identify this virus. In addition, clinical labs and their vendors need enhanced regulatory flexibility to meet these needs. Commercial vendors, who have test materials to detect COVID-19, are restricted from providing guidance on the use of these products, i.e., test methods, because the tests are not FDA cleared. This restriction, which is acceptable at most times, delays the implementation of critically needed assays in times of crisis. We

request that vendors are temporarily released from these restrictions and are allowed to provide guidance for testing for the COVID-19, which will facilitate the implementation and more wide-spread use of these tests.

I urge you to direct the federal government to take immediate action to help our nation's laboratories expand laboratory testing capacity needs as quickly as possible.

As a laboratory professional dedicated to providing quality patient care, I stand ready to assist you in our nation's time of need.

Sincerely,

Sincerely,

(b) (6)

---

**From:** Giroir, Brett (HHS/OASH) [Brett.Giroir@hhs.gov]  
**Sent:** 3/12/2020 8:22:45 PM  
**To:** Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]  
**CC:** Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d509580ef6419b926735f53a2fc3ae-HHS-Keagan.]  
**Subject:** RE: FYSA

copy

Brett P. Giroir, MD  
ADM, US Public Health Service  
Assistant Secretary for Health (ASH)  
200 Independence Avenue, SW  
Washington, DC 20201  
Office Phone: 202-690-7694

-----Original Message-----

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>  
Sent: Thursday, March 12, 2020 8:01 PM  
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Steve Hahn <SH1@fda.hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan (HHS/IOS) <Keagan.Lenihan@hhs.gov>  
Subject: FYSA

(b)(5)

Sent from my iPhone

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/12/2020 8:32:56 PM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Fwd: Expand COVID-19 Testing

Can you work with the team to respond?

Thx

---

**From:** (b) (6)  
**Date:** March 12, 2020 at 6:44:32 PM EDT  
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Subject:** Expand COVID-19 Testing

(b) (6)

March 12, 2020

Dear Stephen M. Hahn,

Dear President Trump:

I am writing as a member of our nation's laboratory medicine team, which includes pathologists and laboratory professionals, to raise my concerns about America's capacity to meet patient testing needs for COVID-19. To date, other countries are doing a better job addressing the diagnostic needs of their patients.

Our government needs to take assertive action to expand the capacity of our nation's clinical laboratories to provide diagnostic testing for the COVID-19 virus in order to hasten its containment. The United States' clinical laboratories are having difficulties securing the resources needed for COVID-19 testing. Labs need an unfettered supply of test kits, instrumentation, reagents and DNA extraction kits, as well as the virus samples necessary to accurately and reliably identify this virus. In addition, clinical labs and their vendors need enhanced regulatory flexibility to meet these needs. Commercial vendors, who have test materials to detect COVID-19, are restricted from providing guidance on the use of these products, i.e., test methods, because the tests are not FDA cleared. This restriction, which is acceptable at most times, delays the implementation of critically needed assays in times of crisis. We request that vendors are temporarily released from these restrictions and are allowed to provide guidance for testing for the COVID-19, which will facilitate the implementation and more wide-spread use of these tests.

I urge you to direct the federal government to take immediate action to help our nation's laboratories expand laboratory testing capacity needs as quickly as possible.

As a laboratory professional dedicated to providing quality patient care, I stand ready to assist you in our nation's time of need.

Sincerely,

Sincerely,  
(b) (6)

**From:** Charrow, Robert (HHS/OGC) [Robert.Charrow@hhs.gov]  
**Sent:** 3/12/2020 8:44:44 PM  
**To:** Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Ray Gorrie, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24cd3c82cff7486092d01d85fb1956a7-HHS-Jennife]; Benor, David E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4b600f66d50459a969e193ba8aadde5-HHS-david.b]; Tress, Deborah W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14527db4b4224120928a31d5c995408f-HHS-dew3-cd]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]  
**CC:** Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6fae2d8d4791dad4-HHS-William]

**Subject:** (b)(5)  
**Attachments:** (b)(5)

Dear All,

(b)(5)  
(b)(5) TX Bob

Robert P. Charrow  
General Counsel  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
(b)(6)  
Email: Robert.Charrow@hhs.gov



**From:** Stimson, Brian (HHS/OGC) [Brian.Stimson@hhs.gov]  
**Sent:** 3/12/2020 9:12:04 PM  
**To:** Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Ray Gorrie, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24cd3c82cff7486092d01d85fb1956a7-HHS-Jennife]; Benor, David E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4b600f66d50459a969e193ba8aadd5-HHS-david.b]; Tress, Deborah W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14527db4b4224120928a31d5c995408f-HHS-dew3-cd]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]  
**CC:** Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6fae2d8d4791dad4-HHS-William]

**Subject:**  
**Attachments:**

(b)(5)

A few line edits for consideration

**From:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>  
**Sent:** Thursday, March 12, 2020 8:45 PM  
**To:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>  
**Cc:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>  
**Subject:** Memo to Support Declaration of National Emergency

<< File

(b)(5)

>>

Dear All,

(b)(5)

(b)(5)

TX Bob

Robert P. Charrow  
General Counsel  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

(b)(6)

Email: Robert.Charrow@hhs.gov

**From:** Ray Gorrie, Jennifer (HHS/OGC) [Jennifer.Ray-Gorrie@hhs.gov]  
**Sent:** 3/12/2020 9:52:32 PM  
**To:** Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Benor, David E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4b600f66d50459a969e193ba8aadde5-HHS-david.b]; Tress, Deborah W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14527db4b4224120928a31d5c995408f-HHS-dew3-cd]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]  
**CC:** Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]  
**Subject:** [REDACTED]  
**Attachments:** [REDACTED].docx

I added some minor edits for your consideration to Brian's version.

**From:** Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>  
**Sent:** Thursday, March 12, 2020 9:12 PM  
**To:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>  
**Cc:** Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>  
**Subject:** RE: [REDACTED]

A few line edits for consideration

<< File: (b)(5) docx >>

**From:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>

**Sent:** Thursday, March 12, 2020 8:45 PM

**To:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>

**Cc:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>

**Subject:** (b)(5)

<< File: (b)(5) >>

Dear All,

(b)(5)

(b)(5)

TX Bob

Robert P. Charrow  
General Counsel  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

(b)(6)

Email: Robert.Charrow@hhs.gov

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/15/2020 4:34:13 PM  
**To:** Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]  
**Subject:** RE: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Thanks David

---

**From:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>  
**Sent:** Sunday, March 15, 2020 4:33 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** RE: Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Hi Denise,  
I did not have any further comments especially on the vaccines or immunotherapy statements.  
Thanks,  
David

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Sent:** Sunday, March 15, 2020 3:55 PM  
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>  
**Subject:** Review Requested by 1620: Talking Points on COVID Therapeutics/Vaccines

Dear Colleagues,

Michael Felderbaum drafted the following and wanting to make sure you've laid eyes on it and have the opportunity to provide comments before it goes to Dr. Hahn if you haven't already.

Thanks,

Denise

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/15/2020 6:36:42 PM  
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
**CC:** Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]  
**Subject:** RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Many thanks to all of you.

Best,

Denise

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Sent:** Sunday, March 15, 2020 5:18 PM  
**To:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>  
**Subject:** RE: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Dear Patrizia,

Thanks for copying us. Nothing to add.

Best Regards,  
Peter

---

**From:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Sent:** Sunday, March 15, 2020 4:39 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>  
**Subject:** Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise  
+ Peter Marks

In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

“could potentially slow the progression of severe respiratory symptoms “

Patrizia

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Date:** March 15, 2020 at 4:16:42 PM EDT

**To:** Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>

**Subject:** Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/16/2020 7:01:58 AM  
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]  
**CC:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]  
**Subject:** FW: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630  
**Attachments:** Therapeutics TPs 03152020 324pm.docx

Good morning Peter,

Did you have any comments in addition to Patrizia's?

Thank you,

Denise

---

**From:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Sent:** Sunday, March 15, 2020 4:39 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>  
**Subject:** Fwd: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Denise  
+ Peter Marks

In the two paragraphs on IL-7 inhibitors and convalescent plasma, respectively , I recommend replacing the section about Reducing/heeding off need for ventilator with :

(b)(5)

Patrizia

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Date:** March 15, 2020 at 4:16:42 PM EDT  
**To:** Farley, John <John.Farley@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>  
**Subject:** Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630

Hi – sorry for short notice – any input before Michael Felberbaum sends to Dr. Hahn?

Thanks,

D



---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 2/27/2020 6:55:34 PM  
**To:** Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
**Subject:** Fwd: FYI--updated FDA statement to issue immediately  
**Attachments:** Supply chain draft statement\_2.27.20\_final to issue\_645pm.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

**From:** "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>  
**Date:** February 27, 2020 at 6:53:41 PM EST  
**To:** "Robinson, Michael J (OS)" <michael.robinson@hhs.gov>, "Hall, Bill (OS)" <bill.hall@hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>  
**Cc:** "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>  
**Subject:** FYI--updated FDA statement to issue immediately

I understand that Keagan and Brian spoke about changes. If any of you have showstoppers, let us know ASAP. We are issuing shortly. Thank you so much!

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/16/2020 5:45:00 PM  
**To:** McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hebert, Angeliq A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angeliq.H]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Stone, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Domanski, Jeffrey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebf0a50f6cd4d7f9-Jeffrey.Dom]; Schweitzer, Roxanne K [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]  
**Subject:** RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No suggested edits – thank you.

Denise

---

**From:** McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 5:43 PM  
**To:** Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>  
**Subject:** RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

No suggested edits from me, thanks!

---

**From:** Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 5:43 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>  
**Subject:** RE: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Agreed.

Is there now an expedited clearance process for these types of messages?

Mitch

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 5:41 PM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>  
**Subject:** Re: Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

Reviewed. This looks good from my perspective.

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 5:23 PM

**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Barth, Janelle <Janelle.Barth@fda.hhs.gov>; Stone, Eric <Eric.Stone@fda.hhs.gov>; Huttenlocker, Denise <Denise.Huttenlocker@fda.hhs.gov>; Domanski, Jeffrey <Jeffrey.Domanski@fda.hhs.gov>; Schweitzer, Roxanne K <Roxanne.Schweitzer@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Barfell, Glenda F <Glenda.Barfell@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>  
**Subject:** Flagging for PDC/CD/ACRA: Commissioner all hands update to go out asap today

(b)(5)

**(b)(5)**

Sincerely,

**Stephen M. Hahn, M.D.**  
**FDA Commissioner**

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/20/2020 7:53:21 AM  
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]  
**Subject:** RE: Bloomberg Time Sensitive Request for Comment  
**Attachments:** COVID-19\_IMG.pptx

Good morning, Patrizia.

Yes, the JIC still exists – I've attached the IMG org chart for reference. Stephanie and Laura also handle other issues that may be sensitive/close hold for the Commissioner and may not go through the JIC.

Best,

Denise

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 7:40 AM  
**To:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shreeve, Chris <Christine.Kueth@fda.hhs.gov>  
**Subject:** RE: Bloomberg Time Sensitive Request for Comment

No response needed. Just flagging for awareness.

**Stephanie Caccomo**

*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk 301.348.1956  
Cell: (b)(6)  
stephanie.caccomo@fda.hhs.gov

---

**From:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 7:39 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shreeve, Chris <Christine.Kueth@fda.hhs.gov>  
**Subject:** Re: Bloomberg Time Sensitive Request for Comment

I am assuming theirs I going to JIC? Is that's still in place ? Everything seems to be sent to everyone at once.  
Patrizia

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Date:** March 19, 2020 at 9:02:58 PM EDT  
**To:** Choe, Lena <Lena.Choe@fda.hhs.gov>, Rawlings, Kimberly <K\_im\_bely.Rawlings@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

**Cc:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>  
**Subject:** FW: Bloomberg Time Sensitive Request for Comment

FYI only on teva.

**Stephanie Caccomo**

*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.348.1956  
Cell: (b)(6)  
stephanie.caccomo@fda.hhs.gov

---

**From:** OS Media (HHS/ASPA) <media@hhs.gov>

**Date:** March 19, 2020 at 8:47:09 PM EDT

**To:** OC OEA OMA-Press <OCOEAOMA-Press@fda.hhs.gov>, Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, Hall, Bill (OS) <bill.hall@hhs.gov>, McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>

**Cc:** OS Media (HHS/ASPA) <media@hhs.gov>

**Subject:** FW: Bloomberg Time Sensitive Request for Comment

Hi

Please see query below

Best,  
Mike

---

**From:** Riley Griffin (BLOOMBERG/ NEWSROOM:) <rgriffin42@bloomberg.net>

**Sent:** Thursday, March 19, 2020 8:39 PM

**To:** OS Media (HHS/ASPA) <media@hhs.gov>; fdaoma@fda.hhs.gov

**Subject:** Bloomberg Time Sensitive Request for Comment

Good evening,

My name is Riley Griffin, I'm a reporter with Bloomberg News.

I'm reaching out with request for comment on a story I'm about to report about Teva's decision to donate 6 million tablets of hydroxychlorone sulfate tablets to U.S. hospitals through wholesalers by March 31, and more than 10 million within a month.

The company has told me that Teva executives held phone calls with senior officials at both HHS and FDA throughout the week, and that the officials requested the drug be made for immediate use to curb the pandemic. As such, Teva's actions are a "direct response that was brought to us by the U.S. government," the company said.

Please let me know should you have comment on those meetings, and those requests.

All the best,

---

Riley Griffin  
Bloomberg News  
212.617.8187 (o)  
**(b)(6)** (c)  
@rileyraygriffin (t)



---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 4/28/2020 2:55:33 PM  
**To:** Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
**Subject:** Fw: Chloroquine Hydroxychloroquine COVID-19 Trials vs date April 16 2020.docx  
**Attachments:** Chloroquine Hydroxychloroquine COVID-19 Trials vs date April 16 2020.docx

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 1:57 PM  
**To:** Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>  
**Subject:** Re: Chloroquine Hydroxychloroquine COVID-19 Trials vs date April 16 2020.docx

Do we get accrual information for these trials as they go along? (I could have a team member chase it down if appropriate)

Seems like an important thing to keep in our line of sight.

---

**From:** Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 1:14 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Chloroquine Hydroxychloroquine COVID-19 Trials vs date April 16 2020.docx

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 7/2/2020 1:11:25 PM  
**To:** Cavazoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
**Attachments:** 2020.07.02 EA Parallel Analysis Summary (2).pptx

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 7/16/2020 11:33:54 AM  
**To:** Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]  
**Subject:** FW: Updated Materials for: 1000-2-CTAP Commisioner's briefing (002).pptx  
**Attachments:** 1000-2-CTAP Commisioner's briefing (002).pptx

Thank you for the update, today. Great work. Please thank your teams.  
Steve

---

**From:** Frank Olivarria <Frank.Olivarria@fda.hhs.gov>  
**Date:** Thursday, July 16, 2020 at 9:51 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Janice Sheehy <Janice.Sheehy@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Susan Flowers <Susan.Flowers@fda.hhs.gov>, Jakea Copeland <Jakea.Copeland@fda.hhs.gov>  
**Subject:** Updated Materials for: 1000-2-CTAP Commisioner's briefing (002).pptx

The slides printed for you this morning have been updated. I just received the updated slide deck, and printed these to the HHS printer.

Colin/Keagan – Dr. Hahn grabbed his own materials this AM, could we make sure we get him this right copy please?  
Thank you!

Frank

---

**From:** Stein, Peter <Peter.Stein@fda.hhs.gov>  
**Sent:** Thursday, July 16, 2020 9:47 AM  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Subject:** 1000-2-CTAP Commisioner's briefing (002).pptx

Frank,  
Sorry, sent you the wrong updated deck, this is the right one,  
peter

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 3/26/2020 8:56:25 AM  
**To:** Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]  
**Subject:** RE: CDRH response update

Thank you.

---

**From:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 8:55 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** RE: CDRH response update

Sure. We will get something together. jw

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 7:49 AM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>  
**Subject:** Fwd: CDRH response update

In an effort to keep SH fully up to speed on what's happening at CDRH, they have started putting these morning reports together. He has a check in with Grogan every morning at 7:45. It would be really helpful to get something similar from CDER and CBER so it was all in one place. There are so many moving pieces, summaries would help catalog the work. Do you think Mary Beth and Julie could put something together like this daily?

Pls.

Sent from my iPhone

Begin forwarded message:

**From:** "Hillebrenner, Elizabeth J" <Elizabeth.Hillebrenner@fda.hhs.gov>  
**Date:** March 26, 2020 at 6:55:12 AM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>  
**Subject:** FW: CDRH response update

Keagan,

Please let me know if I should make any adjustments to the daily emails, such as to the level of detail or otherwise. We want to make sure the Commissioner has what he needs.

Elizabeth

---

**From:** Hillebrenner, Elizabeth J  
**Sent:** Thursday, March 26, 2020 6:52 AM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** CDRH response update

Dr Hahn,

Below please find a list of CDRH's emergency response actions from yesterday as well as anticipated actions in the coming 48 hours.

March 25, 2020 actions

- Ventilators:
  - CDRH issued a blanket **EUA** for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA.
  - CDRH authorized an **EUA** for Beijing Aeonmed Co., Ltd., Beijing, China, for an unapproved ventilator model VG70 that NY state has purchased. The ventilators will be imported next week.
  - A CDRH subject matter expert worked with the FEMA ventilator surprise chain task force to facilitate the availability of a splitter to enable a single ventilator to support multiple patients at one time.
  - CDRH authorized an **EUA** for the Prisma Health 3D printed Ventilator Expansion Splitter (VESper) that allows one ventilator to be used on more than one patient.
  - CDRH met with multiple stakeholders developing creative solutions to a potential ventilator shortage.

(b)(5)

- PPE
  - CDRH published **Guidance** on "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency."
- Diagnostics:
  - CDRH held a Town Hall/Webinar with 1,000 participants during which we provided an overview of the March 16<sup>th</sup> guidance on diagnostics and answered questions from labs.
  - CDRH authorized **EUAs** for SARS-CoV-2 diagnostics from Avellino Labs and Perkin Elmer. Avellino labs notified FDA and was offering their test under the policy outlined in the Feb. 29<sup>th</sup> guidance.
  - We now have 18 authorized diagnostics and over 100 notifications from developers offering tests under the Feb 29<sup>th</sup>/March 16<sup>th</sup> guidance.

Anticipated actions in the next 48 hours

(b)(5)

- CDRH intends to publish Guidance on gowns. The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance
- CDRH intends to publish Guidance on "Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The guidance will address appropriate

labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance.

Elizabeth

**Elizabeth Hillebrenner**

*Associate Director for Scientific and Regulatory Programs*

Center for Devices and Radiological Health

Office of the Center Director

U.S. Food and Drug Administration

Tel: 301-796-6346

[elizabeth.hillebrenner@fda.hhs.gov](mailto:elizabeth.hillebrenner@fda.hhs.gov)



***Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?ID=2000&S=E>.***

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 1/24/2020 4:58:51 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Update re: FDA response to the 2019-nCoV outbreak  
**Attachments:** 02\_2019-nCoV Outbreak\_FDA SITREP\_24 January 2019.docx

FYI

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Date:** January 24, 2020 at 3:24:07 PM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** draft SITREP on the FDA response to the 2019-nCoV outbreak

See attached. Thx - m

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 1/27/2020 5:30:27 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Close Hold: COV Update for the Commissioner  
**Attachments:** 03\_2019-nCoV Outbreak\_FDA SITREP\_27 January 2019.docx

Hi Amy – sending FYSA.

Best,

Denise

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Monday, January 27, 2020 5:05 PM  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** COV Update for the Commissioner

Attached please find today's COV sitrep for the Commissioner. Thanks!



---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/3/2020 4:24:59 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Watters, Sam W (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4731d001d89d45319792bd2fe2490514-HHS-Sam.Wat]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Update: FDA Heads Up for HHS NN - 2/4/20

- **FDA to highlight its work with blood establishments as part of outbreak response**

Today or tomorrow, FDA is expected to highlight that its work in response to the 2019-nCoV includes working with U.S. blood establishments, and that routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood. Further, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus.

---

**From:** Rebello, Heidi  
**Sent:** Monday, February 3, 2020 2:32 PM  
**To:** Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Watters, Sam W (OS) <Sam.Watters@hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** FDA Heads Up for HHS NN - 2/4/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/4/20:

- **FDA to grant first emergency use authorization for novel coronavirus diagnostic test (confidential)**

Tomorrow, FDA is expected to grant the first Emergency Use Authorization for a novel coronavirus diagnostic test. As the outbreak evolves, FDA will communicate around its role in the federal/global response to the outbreak.

- **FDA to announce upcoming workshop on advancing animal testing models for antibacterial drug development**

Tomorrow, FDA is expected to announce a March 5 public workshop to discuss the progress and challenges in the development of various animal testing models for serious infection funded by FDA, NIH and the Biomedical Advanced Research and Development Authority to facilitate antibacterial drug development, and to discuss ideas for future research.

- **FDA to issue guidance for treatments for Sanfilippo Syndrome**

Tomorrow, FDA is expected to issue a draft guidance to industry for the development of treatments for Mucopolysaccharidosis Type III (Sanfilippo Syndrome).

- **FDA to hold public meeting on asbestos in talc and cosmetic products**

Tomorrow, FDA will hold a public meeting on testing methodologies, terminology and criteria for asbestos in talc and cosmetic products manufactured using talc as an ingredient.

- **FDA to announce upcoming meeting on certain OTC antiseptics**

Tomorrow, FDA is expected to announce a March 11 Nonprescription Drugs Advisory Committee to discuss over-the-counter antiseptics in the food handler setting.

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/5/2020 5:05:51 PM  
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]  
**Subject:** FDA nCoV Update February 5, 2020  
**Attachments:** 10\_2019-nCoV Outbreak\_FDA SITREP\_05 February 2020.docx

---

Dear colleagues,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily.

Please be discerning when disseminating further to your staff as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks to all of you for your support.

*Denise*

RADM Denise M. Hinton  
U.S. Public Health Service  
Chief Scientist  
Food and Drug Administration  
Office (301) 796-1090

Internal, confidential

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 2/18/2020 1:49:52 PM  
**To:** Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]  
**CC:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Re: COVID 19 budget

Thanks  
Adding Mimi and Joe

---

**From:** "Tyler, James" <James.Tyler@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 1:49 PM  
**To:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** RE: COVID 19 budget

I will make that work.

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 1:49 PM  
**To:** Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>  
**Subject:** Re: COVID 19 budget

I have a Commissioner meeting at 2:30. Would 3:30-3:40 work? Should be quick.

---

**From:** "Tyler, James" <James.Tyler@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 1:47 PM  
**To:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** RE: COVID 19 budget

Amy, can you chat at 2:30 today? Bill and I are both available. I will send an invite if you are. Thanks

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 1:17 PM  
**To:** Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>  
**Subject:** FW: COVID 19 budget

Hi – Reading your email again, I think that a 5min call will be really helpful. Is there a number that I should call?  
Thanks,  
A

---

**From:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 12:14 PM

**To:** "Tyler, James" <James.Tyler@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** Re: COVID 19 budget

Hi Jay – Let me know if you want to talk for 5 min

---

**From:** "Tyler, James" <James.Tyler@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 12:10 PM  
**To:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** RE: COVID 19 budget

Hi Amy,

Sorry, just seeing this (b)(5)

(b)(5)

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 11:41 AM  
**To:** Tyler, James <James.Tyler@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>  
**Subject:** Re: COVID 19 budget

This is what I am working on

---

**From:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 11:08 AM  
**To:** "Tyler, James" <James.Tyler@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** COVID 19 budget

Hi Jay,  
I have tried to put together a brief budget request related to COVID19. Are you available for a quick conversation?  
Thanks,  
A

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: amy.abernethy@fda.hhs.gov

--

---

**From:** Nguyen, Mimi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=806B10EA0D144541B48BEED0B5E35796-MIMI.NGUYEN]  
**Sent:** 2/18/2020 2:07:01 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Call - COVID 19 Budget  
**Attachments:** Re: COVID 19 budget  
**Location:** Webex  
**Start:** 2/18/2020 3:30:00 PM  
**End:** 2/18/2020 3:40:00 PM  
**Show Time As:** Busy

**Required Attendees:** Tootle, William; Tyler, James



Re: COVID 19 budget

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b)(6)  
887  
Meeting password: (b)(6)

**Join meeting**

**Join by phone**

Tap to call in from a mobile device (attendees only)  
+1-210-795-0506 US Toll  
+1-877-465-7975 US Toll Free  
Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

Need help? Go to <http://help.webex.com>



---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 2/18/2020 3:42:16 PM  
**To:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** FW: COVID 19 budget  
**Attachments:** COVID19 Data.docx

---

**From:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 11:40 AM  
**To:** "Tyler, James" <James.Tyler@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** Re: COVID 19 budget

This is what I am working on

---

**From:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 11:08 AM  
**To:** "Tyler, James" <James.Tyler@fda.hhs.gov>, "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Subject:** COVID 19 budget

Hi Jay,  
I have tried to put together a brief budget request related to COVID19. Are you available for a quick conversation?  
Thanks,  
A

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: amy.abernethy@fda.hhs.gov

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 2/24/2020 5:52:03 AM  
**To:** Andrews, Raymond [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca67b5a5685245dcbb1305065a59876c-Raymond.And]  
**Subject:** Re: Update on FDA response to the novel coronavirus (COVID-19) outbreak

I couldn't agree more.

---

**From:** Andrews, Raymond <RJ.Andrews@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 12:15 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: Update on FDA response to the novel coronavirus (COVID-19) outbreak

This is also the type of communication we might expect to transition to podcast. Just as “innovation labs” were built across bureaucracies we might expect podcast studios to pop up across corporate America.

I'm surprised more haven't imitated A16Z.

---

**From:** A Message from the Commissioner <message@fda.hhs.gov>  
**Sent:** Friday, February 21, 2020 3:44 PM  
**To:** FDA-Wide <FDA-Wide@fda.hhs.gov>  
**Subject:** Update on FDA response to the novel coronavirus (COVID-19) outbreak



## From the Desk of the Commissioner



**U.S. FOOD & DRUG  
ADMINISTRATION**

Dear Colleagues,

I want to share with you some of the critical ways FDA employees are responding to the novel coronavirus (COVID-19) outbreak impacting the world. I know it will come as no surprise that our colleagues from across the agency at all levels are contributing their time and expertise – often working long hours and weekends – to thwart this outbreak.

A central component of our response to COVID-19 is the more than 100 FDA Commissioned Corps Officers from the U.S. Public Health Service, who are currently deployed or have already returned from assignments around the country. I had the chance to join a Corps all-hands meeting today and I am truly impressed by their commitment and leadership in all that they do, including addressing this public health emergency.

Additionally, our staff assigned to the FDA China Office returned to the U.S. with their families. They are returning to work here in the U.S. this week after completing the recommended self-quarantine period and will assist in various international and domestic needs. The health and well-being of our colleagues, and those touched by the virus, remains at the forefront and I know you join me in offering our support to our China Office employees and their families during a challenging time.

Working in coordination with our U.S. and international partners, we are leading efforts on several fronts that fall into the FDA portfolio, including: supporting the biopharmaceutical community on medical countermeasures to combat this disease; real-time monitoring and issue-spotting of the medical product supply chain for any potential disruption;

---

surveilling imported products to assess additional oversight and sampling needs; and tracking down and preventing unscrupulous companies from preying on consumers by touting unlawful “miracle” cures against COVID-19. And, as always, we are leveraging the full breadth of our public health tools to protect the safety and quality of FDA-regulated products for our fellow Americans.

We’ve developed a repository of information related to COVID-19 just for FDA employees on Inside FDA: COVID-19 *Inside FDA*. There you’ll find the latest up-to-date guidance for all employees, including those deployed to work directly on the front lines.

While this is an emerging outbreak, and we have not experienced one quite like this before, we remain resolute in staying vigilant on all counts for the public we serve.

Sincerely,

**Stephen M. Hahn**  
**Commissioner of Food and Drugs**



---

**From:** Franklin, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACE8AF0979A847C59EA26C37C4904883-JOSEPH.FRAN]  
**Sent:** 2/24/2020 1:04:55 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: NYT story on genomic tests

FYI

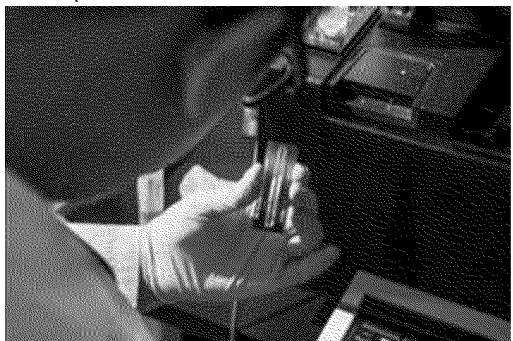
---

**From:** McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 11:53 AM  
**To:** Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
**Subject:** NYT story on genomic tests

**Hi – wanted to share the article below from the NY Times that features a quote from an interview Amy did with the reporter in fall of 2019. At that time, the interview was intended to be part of an article in a series all related to AMR. Despite the months since the interview, the main topic of how genomic tools may be useful in detecting infections remains mostly the same. Please let me know if you have any questions. Best, Megan**

***New Genomic Tests Aim to Diagnose Deadly Infections Faster – Link***

Rapid genomic tests are poised to change the way doctors diagnose and treat infections, but their cost may limit widespread use.



A lab worker prepared to sequence genomes at the University of California San Francisco. Across the country, researchers and engineers are racing to perfect new tests that could revolutionize how doctors diagnose and treat infections. Credit...James Tensuan for The New York Times

**By Andrew Jacobs**

• Feb. 24, 2020, 9:49 a.m. ET

Ryan Springer's mystery illness began last summer with a dull ache in his chest. Over the next few days, the symptoms grew more alarming: sharp pain with every breath, a rapid heartbeat and a spiking fever.

Emergency room doctors at Carle Foundation Hospital in Urbana, Ill., were stumped. They ordered up a lung biopsy and started Mr. Springer, 47, on a broad-spectrum antibiotic. But his condition worsened, and doctors feared he might not survive the five or more days it would take to get the lab results back.

There was one more option: a new genomic test that can offer much faster results by rapidly sorting through the DNA in a blood sample and picking out the pathogen most likely making a patient sick. It is part of a rapidly growing new generation of lab tests under development that could revolutionize the way doctors diagnose and treat infections.

The usual method, based on growing and analyzing germ cultures in a lab, has barely changed since the 1880s, when Julius Petri came up with a way to grow germs in a gelatinous bed of algae set between two nesting discs of glass.

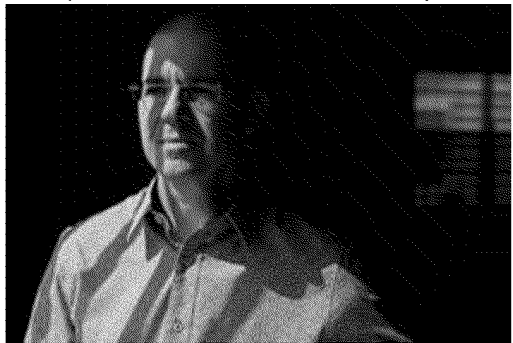
The new genomic diagnostics work by matching the DNA or RNA of microbes in a patient's bodily fluid against vast databases of all known bacteria, viruses or fungi that can sicken humans. Many of the tests produce results in hours, a marked contrast to traditional cultures, which can take days or even weeks to get results — when they work at all. The turnaround in getting test results has become even more urgent with the coronavirus epidemic in China that is spreading around the world.

"We're still using 19th-century technology for most microbiology diagnostics and they just don't work well for many patients," said Kevin Outterson, a professor of health law at Boston University and the executive director of CARB-X, a nonprofit focused on combating antimicrobial resistance. "These new technologies advance what we do by more than a century."

Dr. Amir Khan, an infectious disease specialist, sent Mr. Springer's blood to Karius, a San Francisco-area company that is among a dozen American start-ups developing genomic diagnostic tests.

Less than 48 hours later, the results came back: Mr. Springer had tularemia, or rabbit fever, a rare bacterial infection transmitted by animals and ticks that sickens fewer than 200 Americans a year. It is tough to diagnose — and it can be fatal if untreated.

"The previous case I saw was three years earlier, and it was diagnosed after an autopsy," Dr. Khan said.



Doctors feared Ryan Springer might not survive the time it would take to get lab results back, so his doctor tried an unconventional gambit: a new genomic test, not yet approved by the F.D.A. Credit...Joshua Lott for The New York Times

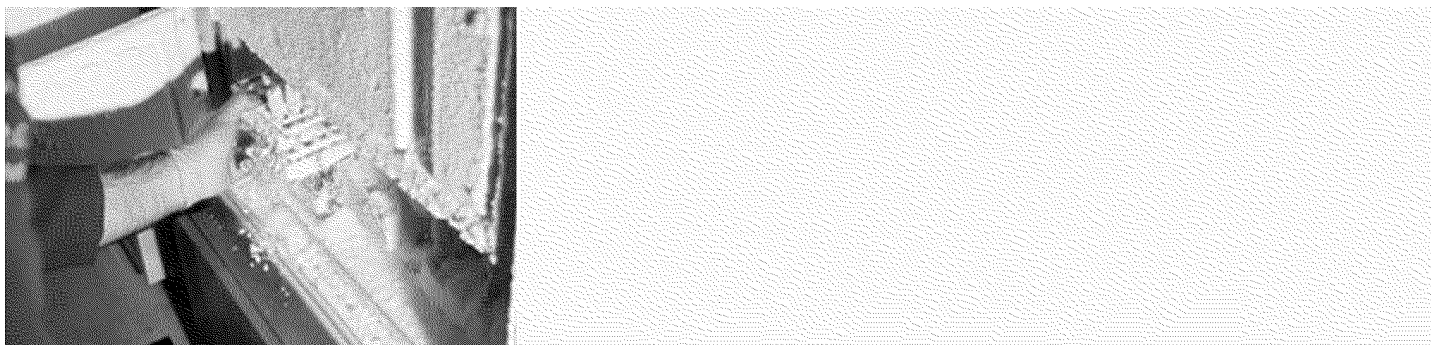
The cure was simple: the antibiotic doxycycline. Mr. Springer took it and was discharged five days later.

The coronavirus outbreak has ratcheted up interest in rapid genomic tests. Developers of the some of the devices say that once the genetic sequence of a novel pathogen has been made publicly available, the information could be quickly uploaded and used to identify those infected.

"With a traditional reference lab, by the time a clinic takes a sample and ships it off, you've lost 12 to 24 hours," said Dr. Jack Regan, the chief executive of LexaGene, a Massachusetts company that hopes to sell its coffee maker-size instrument to airports, schools and clinics. "We can get results in under an hour, which makes a huge difference during deadly outbreaks."

A wider rollout of these tests faces a number of hurdles. Most of the tests identify a patient's infection 80 to 90 percent of the time — regulators would like that figure to be closer to 100 percent — and many of them are still awaiting a green light from the F.D.A. But health experts say a larger impediment to their widespread use is economics: Most of the tests run \$500 to \$3,000 (the test used to diagnose Mr. Springer was \$2,000) and because few private insurances companies cover them, the costs are largely borne by hospitals or patients.

"The technology is incredibly promising but the challenge right now is how to get insurers to pay for it," said Prof. Outterson of Boston University. "We need a system in which hospitals can at least break even for doing the right thing."



Retrieving a plasma sample from a freezer at the University of California, San Francisco. “We believe patients should be treated based on what they’re infected with, not what doctors think they might have,” said one scientist at a genomic testing company. Credit...James Tensuan for The New York Times

John A. Prendergass, associate director of digital health at Ben Franklin Technology Partners, who invests in medical device start-ups, said he was concerned by the high costs, false negatives and low sensitivity of the tests he had looked at.

“The entire diagnostic test space is trying to solve these issues,” he said. “That said, we know one day they are going to be a major component of health care not only in America, but all over the world.”

These diagnostics have little in common with those once promoted by Theranos, the blood-testing company that promised to rapidly diagnose a host of infections through a finger prick, but which turned out to be colossal fraud. Unlike Theranos, which was highly secretive about its technology, the mechanics of these new diagnostics are well understood, and many of the tests are already being road-tested by hospitals across the country as they wait final clearance from the F.D.A.

In addition to saving lives, the new tests could also ameliorate the growing crisis of drug-resistant infections, because pinpointing infections quickly would show doctors which antibiotic to use, rather than resorting to the shot-in-the-dark dispensing of broad-spectrum antibiotics for patients with hard to diagnose infections.

Broad-spectrum antibiotics that act on a wide array of bacteria are commonly used in emergency rooms and intensive care units to combat bloodstream infections, or sepsis, which kill 270,000 Americans a year, accounting for a third of all hospital deaths. Septic shock is also quick to kill, with mortality increasing 8 percent each hour an infection goes untreated.

But at least half of all antibiotics are wrongly prescribed, researchers have found, and some studies suggest that a third of antibiotics prescribed by doctors are unnecessary, many of them dispensed without having a diagnosed infection. Such overuse is one of the major causes of mounting antibiotic resistance as germs mutate to survive.

“We believe patients should be treated based on what they’re infected with, not what doctors think they might have,” said Tom Lowery, the chief scientific officer of T2 Biosystems, a Boston company whose bacteria panel test has been the first to pass muster with the Food and Drug Administration and the Centers for Medicare & Medicaid Services.

As they navigate the regulatory process and work to raise funds, the companies have been putting their tests through clinical studies and trying them out in hospitals and labs across the country.

Dr. Stephen Zekan, a West Virginia surgeon, recently used a test by the company Aperiomics to diagnose what was sickening a 67-year-old woman he initially thought had a tick-borne infection.

“It was frustrating as hell,” he said of the months he spent trying to determine what was causing the woman’s arthritic pain and fatigue. The new test quickly determined that she had tuberculosis.

“I’ve been practicing medicine for 40 years and it’s mind-boggling to think that a supercomputer can go through billions of nucleotides and spit out a result in a few hours,” Dr. Zekan said.

In addition to solving medical mysteries, doctors say the tests could be especially useful to those who are immune-compromised, like cancer patients on chemotherapy or organ transplant recipients, because they often contract dangerous and tough to identify infections.

The array of new products is striking. Arc Bio in Cambridge, Mass., is developing a diagnostics platform that focuses solely on the 400 viruses that make people sick. Day Zero Diagnostics in Boston is field-testing a sequencing and analysis

service that allows hospitals to quickly detect infectious disease outbreaks. And then there is the hand-held gadget made by medical device company BD that allows doctors to rapidly determine whether a patient with a high fever needs an antibiotic for strep throat or simply bed rest for what is most likely a viral respiratory bug.

Another Boston company, Selux Diagnostics, started five years ago in a makeshift lab in the attic of its founder, Dr. Eric Stern, has developed a dishwasher-size machine that can test pathogens against a panel of 60 antibiotics and determine which ones are most likely to work. Unlike standard antibiotic susceptibility tests that take three or more days, Selux's powerful algorithm can yield results within hours of a pathogen being identified from a patient sample.

Dr. William J. Muller, a pediatric infectious disease specialist at Ann & Robert H. Lurie Children's Hospital in Chicago, has used the test created by Karius more than 200 times over the past three years, and said he was impressed by its ability to diagnose lung infections. The test results, he said, have the potential to spare patients lung biopsies, which involve some risk and often yield inconclusive results.

"Anything that reduces the need for painful, invasive procedures should be welcome by hospitals," said Dr. Muller, who has collaborated with Karius in the past and recently published the results of his findings in the journal *Open Forum Infectious Diseases*.

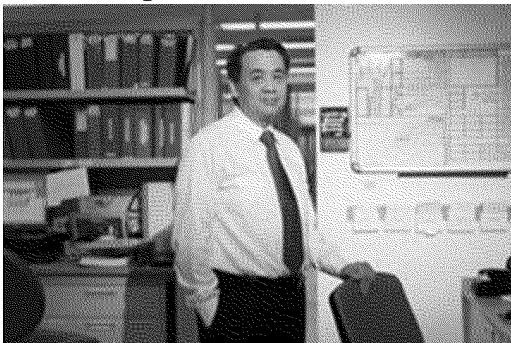
In a separate study published in December in *JAMA Oncology*, doctors at St. Jude Children's Research Hospital in Memphis found that the test was able to predict the onset of life-threatening infections in pediatric leukemia patients three days before the onset of symptoms.



Respiratory samples used for testing at U.C.S.F. A number of mysteries have been solved in this lab, run by Dr. Charles Chiu, including that of a woman who was about to receive a liver transplant but who actually had a treatable form of hepatitis. Credit...James Tensuan for The New York Times

Dr. Amy P. Abernethy, principal deputy commissioner at the F.D.A., who oversees the regulation of new medical devices, said speed remained a concern, given that many of the companies seeking the agency's approval operate proprietary labs, meaning that doctors must send off a blood, urine or fecal sample by overnight mail. That can add a day or more to the sequencing and diagnosis process, a lag that can be fatal for sepsis patients.

"We have a fair amount of excitement over next-generation sequencing, but we do acknowledge a few practical hurdles we need to get over," she said in an interview.



Dr. Chiu in the office of his microbiology lab at U.C.S.F. Credit...James Tensuan for The New York Times

The excitement is also tempered by a hard-nose reality: although administrators of Medicaid and Medicare recently agreed to cover 65 percent of the cost for the T2 Biosystems test for the first two or three years, most insurance

companies will not pay for genomic diagnostics without federal approval and peer-reviewed clinical studies that can definitively establish their efficacy, a process that can take years.

Dr. Charles Chiu, a professor of laboratory medicine at University of California, San Francisco, and the director of a lab that is developing its own genomic sequencing platform, said many insurers remained unconvinced that the new tests were cost effective, despite scores of cases that led to reduced health care costs, shortened hospital stays and saved lives.

He listed a number of mysteries solved by his lab's sequencing tests, and documented last year in *The New England Journal of Medicine*. They included a Los Angeles woman with liver failure who was scheduled for a liver transplant — at the cost of \$1 million — but who it turned out had a rare, treatable form of hepatitis. Then there was the 14-year-old boy desperately ill with meningitis who had to be put in a medically induced coma because doctors could not figure out what was causing his brain to swell.

After months of inconclusive cultures, genomic testing pointed to leptospirosis, an extremely rare bacterial infection that is easily treated with old-school penicillin.

"Insurance companies won't think twice about covering a \$4,000 cancer gene panel," Dr. Chiu said, "so why not cover an infectious disease test that can save a child's life?"

Andrew Jacobs is a reporter with the Health and Science Desk, based in New York. He previously reported from Beijing and Brazil and had stints as a Metro reporter, Styles writer and National correspondent, covering the American South. @AndrewJacobsNYT

**Megan McSeveney**

*Press Officer*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cell:

(b)(6)

Megan.McSeveney@fda.hhs.gov





---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 2/28/2020 5:57:07 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Fw: Request for FDA EUA exemption  
**Attachments:** FDA.coronavirus.final.docx

FYI

---

**From:** Vince Stine <VStine@aacc.org>  
**Sent:** Friday, February 28, 2020 1:06 PM  
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Request for FDA EUA exemption

Dr. Hahn,

I am attaching a letter from the American Association for Clinical Chemistry requesting that the Food and Drug Administration (FDA) exercise its enforcement discretion to permit qualified laboratories to use laboratory developed tests to detect SARS-CoV-2 and diagnose COVID-19. We appreciate your consideration of our request.

Sincerely

Vincent Stine, PhD  
Senior Director, Government & Global Affairs  
American Association for Clinical Chemistry

**Vince Stine, PhD**  
Senior Director, Government Affairs  
AACC | 900 Seventh Street, NW, Suite 400 | Washington, DC 20001

P +1 202.835.8721  
VStine@aacc.org  
www.aacc.org



---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 3/2/2020 2:48:47 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]  
**Subject:** FDA Heads Up for HHS NN - 3/3/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 3/3/20:

- **FDA to highlight actions in response to COVID-19 outbreak**

Tomorrow and this week, FDA is expected to highlight the agency's work in diagnostics, the global supply chain and other activities being done to support the COVID-19 response. Upcoming topics include FDA warning letters to companies for false claims of treating COVID-19 and the role of the PHS in response.

- **FDA Commissioner to testify on COVID-19 response efforts**

Tomorrow, at 10 a.m., FDA Commissioner Dr. Stephen Hahn is expected to testify before Senate HELP at a hearing on "An Emerging Disease Threat: How the U.S. is Responding to COVID-19, the Novel Coronavirus."

- **FDA effort to help consumers better understand GMOs**

Tomorrow, FDA is expected to launch a new 'Feed Your Mind' initiative to increase consumer understanding of genetically modified foods, in collaboration with EPA and USDA.

- **FDA to increase warning risk of neuropsychiatric events associated with asthma and allergy medication for Singulair (confidential)**

Tomorrow, FDA is expected to require a boxed warning – the agency's most prominent warning – for Singulair and

generics to strengthen an existing warning about the risk of neuropsychiatric events associated with the drug which is used to treat asthma and allergic rhinitis (allergies).

- **FDA to issue medical device cybersecurity-related safety communication (confidential)**

Tomorrow, FDA is expected to issue a Safety Communication about the SweynTooth family of cybersecurity vulnerabilities, which may introduce risks for certain medical devices as well as many consumer wearables and internet connected home devices.

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/3/2020 8:25:01 AM  
**To:** Morgan, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd7d5fd26bf04d5aa9f3393c8d419685-Michael.Mor]  
**Subject:** Re: Drones. Disinfecting robots. 'Contactless' deliveries. The coronavirus outbreak is a test for China's tech industry - CNN

This is fascinating. And shows the speed in development cycles in China.

---

**From:** Morgan, Michael <Michael.Morgan@fda.hhs.gov>  
**Sent:** Tuesday, March 3, 2020 8:19 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Drones. Disinfecting robots. 'Contactless' deliveries. The coronavirus outbreak is a test for China's tech industry - CNN

Amy,

This is very interesting as well.

How technology is being deployed to fight coronavirus in China.

<https://www.cnn.com/2020/02/23/tech/china-tech-coronavirus-outbreak/index.html>

Best,

Mike

---

**From:** Nguyen, Mimi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=806B10EA0D144541B48BEED0B5E35796-MIMI.NGUYEN]  
**Sent:** 3/3/2020 3:45:13 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** FW: UPDATE #2 (2/28) - Commissioner's Appropriations Hearing Binder  
**Attachments:** Written Testimony.pdf; Cell Culture Technology - REVISED.pdf; Buildings and Facilities - Infrastructure - REVISED.pdf; Prep 1 Agenda and Hot Topic Q&A.pdf; Outstanding Letters (2.28.20).pdf; Azar Hearing Summaries - Week of 2-24-20.docx

**Importance:** High

Hi Amy,

There have been a few updates to the appropriations binder contents. Since you have the binder and I won't see you until next week, I wanted to make sure you could see all the updated documents. I already printed the new inserts and they are on your desk labeled Binder Inserts.

Cheers,  
Mimi

---

**From:** Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Sent:** Friday, February 28, 2020 12:44 PM  
**To:** Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Flowers, Susan <Susan.Flowers@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; John, Inzinga <Inzinga.John@fda.hhs.gov>; Vega, Jacqueline <Jacqueline.Vega@fda.hhs.gov>; Smith, Crystal <Crystal.Smith@fda.hhs.gov>; Singh, Patrice <Patrice.Singh@fda.hhs.gov>; Newman, Angela <Angela.Newman@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; Sobel, Isabel <Isabel.Sobel@fda.hhs.gov>; Bess, Demetrice <Demetrice.Bess@fda.hhs.gov>; Fawundu, Yatta <Yatta.Fawundu@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; OO-OFBA-Congressional-Government <OO-OFBA-Congressional-Government@fda.hhs.gov>  
**Subject:** RE: UPDATE #2 (2/28) - Commissioner's Appropriations Hearing Binder  
**Importance:** High

Apologies—minor update to the intro language of the Hearing Summary document.

---

**From:** Nguyen, Michael A.  
**Sent:** Friday, February 28, 2020 12:10 PM  
**To:** Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Flowers, Susan <Susan.Flowers@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; John, Inzinga <Inzinga.John@fda.hhs.gov>; Vega, Jacqueline <Jacqueline.Vega@fda.hhs.gov>; Smith, Crystal <Crystal.Smith@fda.hhs.gov>; Singh, Patrice <Patrice.Singh@fda.hhs.gov>; Newman, Angela <Angela.Newman@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; Sobel, Isabel <Isabel.Sobel@fda.hhs.gov>; Bess, Demetrice <Demetrice.Bess@fda.hhs.gov>; Fawundu, Yatta <Yatta.Fawundu@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; OO-OFBA-

Congressional-Government <OO-OFBA-Congressional-Government@fda.hhs.gov>

**Subject:** UPDATE #2 (2/28) - Commissioner's Appropriations Hearing Binder

**Importance:** High

All,

I'm reaching out with updates to the Commissioner's binder. Please update your binders prior to the Commissioner's 11AM prep session next Mon. 2<sup>nd</sup> with CFSAN, OFPR, CVM, and ORA.

Below you'll find a chart that provides a breakdown of the attached updates, along with the respective instruction.

Please let me know if you have any questions.

Best,

Mike

(b)(5)

---

**From:** Nguyen, Michael A.

**Sent:** Thursday, February 20, 2020 3:12 PM

**To:** Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Flowers, Susan <Susan.Flowers@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; John, Inzinga <Inzinga.John@fda.hhs.gov>; Vega, Jacqueline <Jacqueline.Vega@fda.hhs.gov>; Smith, Crystal <Crystal.Smith@fda.hhs.gov>; Singh, Patrice <Patrice.Singh@fda.hhs.gov>; Newman, Angela <Angela.Newman@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; Sobel, Isabel <Isabel.Sobel@fda.hhs.gov>; Bess, Demetrice <Demetrice.Bess@fda.hhs.gov>

**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>

**Subject:** UPDATE #1 (2/21) – Commissioner's Appropriations Hearing Binder

**Importance:** High

Good afternoon all,

I'm writing to let you know that the Office of Congressional Appropriations (OCA) intends to distribute to you or your principles, copies of the Commissioner's Hearing prep binder for his respective March 11 and March 24 hearings before the House and Senate Appropriations Committees regarding the FY2021 President's Budget Request. Apart from the Commissioner himself, copies of binders are being provided to:

- Keagan Lenihan
- Amy Abernathy
- Carly McWilliams
- Anand Shah
- Jim Sigg
- Angel Herbert
- James Tyler
- Bill Tootle
- Erika Anderson
- Colin Rom
- Karas Gross
- Nick Alexander
- Maren McBride
- Stacy Amin
- Laura Caliguiri
- Heather Janik

OCA will begin distributing binders between 4-5PM today. **Please let me know as soon as possible, where we can meet you with your, or your principle's, binder.**

As I have done in prior years, I will periodically email with updates to the binders, along with instructions (i.e. add new material, swap a document out, etc.). I'll need your assistance in updating the binders in short order to ensure that on any particular day, your or your principle's binder remains identical to the Commissioner's binder.

As hearing lead, I look forward to working with you all! Never hesitate to reach out to me should you have any question:

(b)(6)

Best,

Mike

Michael A. Nguyen, MHA  
*Medical Products and Tobacco Team Lead*

Office of Congressional Appropriations  
U.S. Food and Drug Administration

(b)(6)

michael.nguyen1@fda.hhs.gov

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/4/2020 7:42:47 AM  
**To:** Ursheet Parikh [uparikh@mayfield.com]  
**Subject:** Re: Latest FDA guidance on Covid-19 diagnostics

Hi Ursheet,  
Thank you for the info. Really interesting.  
I hope that you are well.  
Take care,  
Amy

---

**From:** Ursheet Parikh (b)(6)  
**Sent:** Wednesday, March 4, 2020 12:16 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Latest FDA guidance on Covid-19 diagnostics

Amy, thought I'd share with you how the guidance from the weekend is unleashing with high velocity the development of new tests very fast.  
Here is a story from the local paper on what is happening in the Bay Area -  
<https://www.mercurynews.com/2020/03/03/coronavirus-how-to-find-hidden-infections-stanford-and-uc-fast-track-new-tests/>  
Hopefully we see these tests hit volume soon.

(b)(4)

Best,  
Ursheet



---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/4/2020 8:15:33 AM  
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]  
**Subject:** Re: Meeting Request - Low-Cost Breathing Device Developed by Harvard/MIT Alumni for COVID-19

Thanks so much, Suzanne.  
Take care and enjoy your day

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Sent:** Wednesday, March 4, 2020 8:11 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Subject:** Re: Meeting Request - Low-Cost Breathing Device Developed by Harvard/MIT Alumni for COVID-19

Amy,

I've made the connection for Sanchay within CDRH.

Suzanne

Suzanne B. Schwartz, MD, MBA  
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)  
Center for Devices & Radiological Health  
US Food & Drug Administration  
Office: 301-796-6937  
Mobile: 202-841-9996

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Date:** March 4, 2020 at 7:41:06 AM EST  
**To:** Sanchay\_Gupta@hms.harvard.edu <Sanchay\_Gupta@hms.harvard.edu>, shaheerpiracha@gmail.com <shaheerpiracha@gmail.com>  
**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Fw: Meeting Request - Low-Cost Breathing Device Developed by Harvard/MIT Alumni for COVID-19

Hi Sanchay,

Thank you for your message. I am forwarding this to our Devices Center (CDRH) for triage.

Kind regards,

Amy

cc: Jeff Shuren, Suzanne Schwartz, Denise Hinton, Michael Mair, Joe Franklin

---

**From:** Gupta, Sanchay (b)(6)  
**Sent:** Wednesday, March 4, 2020 1:45 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Shaheer Piracha (b)(6)  
**Subject:** Meeting Request - Low-Cost Breathing Device Developed by Harvard/MIT Alumni for COVID-19

Hi Dr. Abernethy,

My name is Sanchay Gupta and I am leading efforts out of Harvard Medical School and the Harvard Innovation Lab to expand ventilator capacity as part of ongoing epidemic preparedness efforts. Through close collaboration with pulmonary and critical care doctors in the U.S., our team from Harvard and MIT has developed a reliable, low-cost, and portable breathing device that can be used in epidemic scenarios where the demand for ventilators may vastly outpace the available supply (b)(4)

(b)(4)

I am attaching an executive summary which further details our solution. Please let me know if you might be able to spare 15 minutes for a quick call.

Thank you in advance for your time.

Very Best,  
Sanchay Gupta  
Co-Founder at Umbulizer  
(b)(6)

---

**From:** Lilly, Trudy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FFF918A5EAAF496EB9F98728A1B0C242-LILLYT]  
**Sent:** 3/5/2020 1:26:51 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Desai, Vid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91b722d8adf748aaa8e91f77ad37a272-Vidyut.Desai]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Berrellez, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfaa6cc191f447659c6ab592b78f4af4-Jessica.Ber]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Subject:** FDA: Slated to receive \$61M to combat Corona Virus  
**Attachments:** 3-5 Coronavirus.docx

This is really happening – see below.

---

**From:** Staffa, Edward <Edward.Staffa@fda.hhs.gov>  
**Sent:** Thursday, March 05, 2020 7:50 AM  
**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Temple, Robert <Robert.Temple@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Cc:** Ahadpour, Mitra <Mitra.Ahadpour@fda.hhs.gov>; Amatrudo, Kathryn <Kathryn.Amatrudo@fda.hhs.gov>; Anagnostiadis, Eleni <Eleni.Anagnostiadis@fda.hhs.gov>; Arnold, Nathan <Nathan.Arnold@fda.hhs.gov>; Ashley, Donald <Donald.Ashley@fda.hhs.gov>; Ball, Robert <Robert.Ball@fda.hhs.gov>; Baumgartner, Kristofer <Kristofer.Baumgartner@fda.hhs.gov>; Beach, Carter <Carter.Beach@fda.hhs.gov>; Behr, Virginia L <Virginia.Behr@fda.hhs.gov>; Bennett, Carol <Carol.Bennett@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>; Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Brown, Elizabeth <Elizabeth.Brown@fda.hhs.gov>; Buckman, Paul <Paul.Buckman@fda.hhs.gov>; Buckman-Garner, ShaAvhrée <ShaAvhree.Buckman-Garner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Cannon, Patrick <Patrick.Cannon@fda.hhs.gov>; Cunningham, Courtney C. <CourtneyC.Cunningham@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; CDER Trade Press <CDERTradePress@fda.hhs.gov>; Chen, Qi <Qi.Chen@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Clark-Lynn, Sarah <Sarah.Clark-Lynn@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Cox, Lucinda <Lucinda.Cox@fda.hhs.gov>; Dal Pan, Gerald <Gerald.DalPan@fda.hhs.gov>; Defina, Matt <Matt.Defina@fda.hhs.gov>; Dermody, Colleen <Veronica.Dermody@fda.hhs.gov>; Derr, Nancy E <Nancy.Derr@fda.hhs.gov>; Echegoyen, Edwin <Edwin.Echegoyen@fda.hhs.gov>; ElZarrad, M. Khair <Mohammed.ElZarrad@fda.hhs.gov>; Falconer, Monique <Monique.Falconer@fda.hhs.gov>; Farchione, Tiffany <Tiffany.Farchione@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Fuchs, Elissa <Elissa.Fuchs@fda.hhs.gov>; Guerrier, Natasha <Natasha.Guerrier@fda.hhs.gov>; Haghpanah, Sepideh <Sepideh.Haghpanah@fda.hhs.gov>; Hennessey, Lyndsay <Lyndsay.Hennessey@fda.hhs.gov>; Huang, Sheilyn <Sheilyn.Huang@fda.hhs.gov>; Hunter, Nina L <Nina.Hunter@fda.hhs.gov>; Ikenberry, Sarah <Sarah.Ikenberry@fda.hhs.gov>; Iles, Irina \* <Irina.Iles@fda.hhs.gov>; Jackler, Karen <Karen.Jackler@fda.hhs.gov>; Jerrick, Morgan <Morgan.Liscinsky@fda.hhs.gov>; JW Direct Reports & Deputies <JWDirectReportsandDeputies@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Kim, Sarah <Sarah.Kim@fda.hhs.gov>; Kopcha, Michael <Michael.Kopcha@fda.hhs.gov>; Kornegay, Cynthia J <Cynthia.Kornegay@fda.hhs.gov>; Kremzner, Mary E <Mary.Kremzner@fda.hhs.gov>; Laine, Susan <Susan.Laine@fda.hhs.gov>; Lambert, Tu-Van <TuVan.Lambert@fda.hhs.gov>; Lappin, Brian <Brian.Lappin@fda.hhs.gov>; Lee, Tracey (FDA) <Tracey.Lee@fda.hhs.gov>; Levy, Michael (CDER)

<Michael.Levy@fda.hhs.gov>; Lilly, Trudy <Trudy.Lilly@fda.hhs.gov>; Lowy, Naomi <Naomi.Lowy@fda.hhs.gov>; Margolis, Katherine <Katherine.Margolis@fda.hhs.gov>; Maynard, Janet <Janet.Maynard@fda.hhs.gov>; McCune, Susan <Susan.McCune@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Meadows, Michelle <Michelle.Meadows@fda.hhs.gov>; Menon, Ramesh <Ramesh.Menon@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Meyer, Tamra <Tamra.Meyer@fda.hhs.gov>; Moeny, David <David.Moeny@fda.hhs.gov>; OGDREQUEST <OGDREQUEST@fda.hhs.gov>; O'Grady, Jacob <Jacob.Ogrady@fda.hhs.gov>; O'Grady, Jordana <Jordana.OGrady@fda.hhs.gov>; CDER OSE OCT <CDEROSEOCT2@fda.hhs.gov>; Pattee, Suzanne <Suzanne.Pattee@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Phucas, Kristin <Kristin.Phucas@fda.hhs.gov>; Pincock, Laura <Laura.Pincock@fda.hhs.gov>; Pinheiro, Simone P <Simone.Pinheiro@fda.hhs.gov>; Pippins, Jennifer R. <Jennifer.Pippins@fda.hhs.gov>; Rausch, Paula (FDA) <Paula.Rausch@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Rowzee, Anne <Anne.Rowzee@fda.hhs.gov>; Ruddy, Michelle <Michelle.Ruddy@fda.hhs.gov>; Ruiz, Diane <Diane.Ruiz@fda.hhs.gov>; Cheaves, Sarita <Sarita.Cheaves@fda.hhs.gov>; Schwemer, Tawni <Tawni.Schwemer@fda.hhs.gov>; Settle, Jill <Jill.Settle@fda.hhs.gov>; Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Slack, Mary Ann <Maryann.Slack@fda.hhs.gov>; Smalls, Fallon <Fallon.Smalls@fda.hhs.gov>; Smith, Harry <Harry.Smith@fda.hhs.gov>; Sokolowska, Marta <Marta.Sokolowska@fda.hhs.gov>; Staffa, Edward <Edward.Staffa@fda.hhs.gov>; Staffa, Judy A <Judy.Staffa@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Staton, Anna <Anna.Staton@fda.hhs.gov>; Stein, Peter <Peter.Stein@fda.hhs.gov>; Temple, Robert <Robert.Temple@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Toigo, Theresa A <Theresa.Toigo@fda.hhs.gov>; Toufanian, Maryll <Maryll.Toufanian@fda.hhs.gov>; Trivedi, Aalap <Aalap.Trivedi@fda.hhs.gov>; Unger, Ellis <Ellis.Unger@fda.hhs.gov>; Unger, Monica <Monica.Unger@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Wiggins, Thelma <Thelma.Wiggins@fda.hhs.gov>; Williams, Christina <Christina.Williams@fda.hhs.gov>; Williams, Renee (Tchoulakian) <Renee.Williams2@fda.hhs.gov>; Winthrop, Sally <Sally.Winthrop@fda.hhs.gov>; Yu, Lawrence <Lawrence.Yu@fda.hhs.gov>

**Subject:** FW: The FDA News Summary for Thursday, March 05, 2020

Good morning... in the clips today

## COVID-19 Coverage (possibly more CDER/FDA specific)

**Opinion: Don't Count On Seeing A Coronavirus Vaccine Anytime Soon.** In an op-ed for National Review, physician and former FDA official Henry Miller writes that, despite the hype from the media and politicians, developing a vaccine for the novel coronavirus will not be a quick process. In his article, Miller explains the steps that must be taken to develop, test and trial a vaccine and concludes: "A coronavirus vaccine in the foreseeable future? In spite of the rosy predictions by politicians and pundits, don't count on it."

**House Approves \$8.3B Spending Bill To Combat Novel Coronavirus --- \$61M for FDA** The Washington Post reports "the House overwhelmingly approved an \$8.3 billion emergency spending bill Wednesday to combat the coronavirus, sending the legislation to the Senate, which could act as soon as Thursday." According to the Post, "President Trump is expected to sign the legislation, which is more than triple the size of the White House's budget request from last week." The spending bill "sends billions to address nearly every aspect of the outbreak, from vaccine research and development, to support for state and local public health agencies, to medical supplies and preparation at home and abroad." The House's vote was 415-2. Trump, while visiting NIH on Tuesday, said, "We're doing very well in terms of getting the funding we need, the necessary funding. I asked for X, and they want to give us more than X, and that's okay." The New York Times reports the bipartisan package "includes nearly \$7.8 billion for agencies dealing with the virus and came together after days of intensive negotiations." The package "also authorizes roughly \$500 million to allow Medicare providers to administer telehealth services so that more elderly patients, who are at greater risk from the virus, can receive care at home." The spending bill "would also reimburse \$136 million that the administration had previously transferred from other programs in" HHS. It "would provide \$6.5 billion for" HHS, "with \$2.2 billion designated specifically for" CDC and \$836 million for NIH. Meanwhile, the FDA "would receive \$61 million." The piece adds that House legislators on Wednesday "attended closed-door briefings with Vice

President Mike Pence...and other top health officials, including” NIAID Director Anthony Fauci. The Wall Street Journal reports the deal urges HHS Secretary Alex Azar to use his authority to make sure the price of any vaccine for the novel coronavirus is affordable. It also asserts that Azar should not postpone the vaccine’s development. USA Today reports that “the package includes more than \$3 billion for research and the development of vaccines and \$2.2 billion that will help in prevention, preparedness and response.” The package “also allocates \$1 billion for state and local response, about half of which would go to specific cities.” Under the proposal, “each state would receive no less than \$4 million.” The Los Angeles Times reports “Senate Majority Leader Mitch McConnell said he is ‘optimistic’ lawmakers can approve legislation this week and send it to President Trump, who is expected to sign it.” For his part, “Senate Democratic Leader Charles E. Schumer (D-N.Y.) said Wednesday the bill will include \$950 million for state and local governments, including \$350 million for ‘hot spot’ areas affected by the outbreak, \$500 million for masks, protective equipment and other medical supplies for states, local governments and hospitals, and \$100 million for community health centers and funding for training and beds.” The AP reports “the 415-2 vote came after House Speaker Nancy Pelosi beat a tactical retreat on vaccine price guarantees and followed a debate that lasted only a few minutes.” The article says “the Senate is likely to pass the measure Thursday and send it to the White House for Trump’s signature.” Reuters reports that “in a bid to also help control the spread of the virus outside the United States, \$1.25 billion would be available for international efforts.” GOP lawmakers “cited a \$7.8 billion cost for the bill, instead of \$8.3 billion. That does not include \$500 million authorized for a ‘telehealth’ program for senior citizens.” NBC News reports “the bill includes a provision that would require that funds are used only to fight the coronavirus and other infectious diseases, as some Democrats feared that the Trump administration could raid the funding and use it for other unrelated purposes.” The President “had asked Congress for \$2.5 billion to combat the virus, but Democrats quickly said that amount would be insufficient and noted that it called for taking money from programs for the poor.” CNBC reports “the plan also allows an estimated \$7 billion in low-interest Small Business Administration loans to affected small businesses.” Politico reports on the spending bill, and says “half hour, back-to-back briefings on Wednesday frustrated some lawmakers, who complained that there was not nearly enough time to question Pence and other Trump administration health officials.” FDA Commissioner Stephen Hahn, Fauci, “and White House coronavirus response coordinator Deborah Birx...joined Pence at the briefings.” Among other news outlets CBS News CNN Forbes The Hill U.S. News & World Report Washington Examiner CQ Roll Call NPR Atlanta Journal-Constitution Connecticut Mirror Intelligencer (NY) Modern Healthcare Financial Times also report.

## CDER/FDA In The News --- NON COVID-19

**Joe Biden Unveils Plan To Tackle Opioid Crisis.** McClatchy reports, “Former Vice President Joe Biden says he would combat the opioid crisis by banning pharmaceutical companies from making payments or providing incentives for physicians to prescribe their products,” and his “campaign unveiled a list of proposals Wednesday [unable to find complete plan online] aimed at curbing opioid addiction, just six days ahead of the March 10 Missouri primary.

**FDA Announces Merck’s Singulair Must Have Boxed Warning About Risk Of Neuropsychiatric Events.** Following this 3/4 FDA DSC, Fox Business reports the FDA on Wednesday announced that the asthma medication Singulair (montelukast), sold by Merck, must now “have a prominent warning, called a ‘boxed warning,’ about the risk of neuropsychiatric events, according to an FDA press release.” The article quotes CDER’s DPARP Director Sally Seymour saying, “We recognize that millions of Americans suffer from asthma or allergies and rely on medication to treat these conditions,” adding, “The incidence of neuropsychiatric events associated with montelukast is unknown, but some reports are serious, and many patients and health care professionals are not fully aware of these risks.” The Miami Herald also covers the story.

**New Mexico Governor Signs Four Health-Related Bills That Include Price Caps On Insulin, Path To Importing Drugs From Canada.** The AP reports Gov. Michelle Lujan Grisham (D-NM) signed four “health-related bills Wednesday that include consumer financial protections to ensure access to insulin for diabetics and new possibilities for state-marketed insurance plans that limit out-of-pocket costs.” One bill “caps prices paid by diabetes patients for insulin prescriptions at \$25 for a one-month supply.” Another bill signed by Grisham “opens the way for New Mexico to pursue imports of prescription drugs from Canada on a wholesale basis in search of cost savings.” Santa Fe New Mexican also reports.

## Other Opioid News

No additional today

## Other COVID-19 News

See Separate attached Word document and...

additional links below (from different sources, may overlap/duplicate)

- [U.S. CDC Reports 129 Coronavirus Cases, Including Those Under Investigation](#)
- [HHS Secretary Alex Azar Encouraged By Proposed Coronavirus Vaccine Timeline](#)
- [HHS Clarifies US Has About 1% Of Face Masks Needed For 'Full-Blown' Coronavirus Pandemic](#)
- [Nursing Homes Are Starkly Vulnerable To Coronavirus: The Coronavirus Outbreak](#)
- [Coronavirus Task Force Rolls Out Guidelines For Nursing Homes](#)
- [After Family Gets Coronavirus, New York Suburb Is Gripped By Anxiety: The Coronavirus Outbreak](#)
- [Coronavirus Fears Change Art Of Shaking Hands In US Capital](#)
- [Obama Urges Public To 'Stay Calm' And 'Listen To The Experts' On Coronavirus](#)
- [First Veteran Coronavirus Case Confirmed By Trump's VA Secretary](#)
- [U.S. Health System Is Showing Why It's Not Ready For A Coronavirus Pandemic](#)
- [Pence And Trump Take Different Paths During Coronavirus Outbreak](#)
- [As Coronavirus Spreads, The People Who Prepare Your Food Probably Don't Have Paid Sick Leave](#)
- [Amid A Global Crisis, Trump Keeps Lying And Misleading About Pretty Much Everything](#)
- [Trump's Coronavirus Response Puts His Authoritarian Instincts On Full View](#)
- [Coronavirus Shut Down Mona Lisa And James Bond. We Can't Let It Isolate Us.](#)
- [Coronavirus Tests Trump's Credibility Gap](#)
- [Coronavirus Anxiety Is Everywhere, And There Is No Cure](#)
- [Trump Meets With U.S. Airline Executives Amid Coronavirus Outbreak](#)
- [Researchers Identify Two Coronavirus Strains As China Cases Dwindle](#)
- [Coronavirus Testing Offered With Just A Doctor's Approval, C.D.C. Says: The Coronavirus Outbreak](#)
- [Want A Coronavirus Vaccine, Fast? Here's A Solution](#)
- [Expanded Coronavirus Testing May Overwhelm Lab Capacity, Say Some Experts](#)
- [Fauci Says It's Still Too Early To Determine U.S. Death Rates From Coronavirus Outbreak](#)
- [Coronavirus Spread From China. Now, China Doesn't Want The World Spreading It Back.](#)
- [Anti-virus Measures Take Drastic Turns In Saudi, Iran, Italy](#)
- [Despite Virus, IOC Unwavering On Olympics Starting In July](#)
- [Thousands Wait For Hospital Beds In South Korea As Coronavirus Cases Surge](#)
- [Italian Coronavirus Death Toll Jumps To 107, All Schools Shut](#)
- [Coronavirus Cases In Britain Rise To 85 In Biggest Daily Jump](#)
- [Germany Reports 44 New Confirmed Coronavirus Cases In Germany](#)
- [France Says It Now Has 285 Confirmed Cases Of Coronavirus](#)

**From:** Bulletin Intelligence <FDA@BulletinIntelligence.com>

**Sent:** Thursday, March 05, 2020 6:14 AM

**To:** FDA@bulletinintelligence.com

**Subject:** The FDA News Summary for Thursday, March 05, 2020

This morning's FDA News Summary is attached.

**Website:** You can also read today's briefing, including searchable archive of past editions, at <http://FDA.BulletinIntelligence.com/>.

**Full-text Links:** Clicking the hypertext links in our write-ups will take you to the newspapers' original full-text articles.

**Interactive Table of Contents:** Clicking a page number on the table of contents page will take you directly to that story.

**Contractual Obligations and Copyright:** This copyrighted material is for the internal use of FDA employees only and, by contract, may not be redistributed without Bulletin Intelligence's express written consent.

**Contact Information:** Please contact us any time at 703-483-6100 or [FDA@BulletinIntelligence.com](mailto:FDA@BulletinIntelligence.com). Use of this email address will automatically result in your message being delivered to everyone involved with your service, including senior management. Thank you.

**Unsubscribe:** This copy of the FDA News Summary was sent to you because you are registered for email notification on our website. If you would like to cancel email delivery click [here](#).

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:43:09 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Fw: FDA 2019-nCOV SITREP - 06 Feb 2020  
**Attachments:** 11\_2019-nCoV Outbreak\_FDA SITREP\_06 February 2020.docx  
**Flag:** Flag for follow up

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Thursday, February 6, 2020 7:02 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>  
**Subject:** FDA 2019-nCOV SITREP - 06 Feb 2020

Hi,

Attached for your situational awareness is the 06 February FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks to all of you for your support.

-Michael



---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:43:22 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Fw: FDA 2019-nCOV SITREP - 07 Feb 2020  
**Attachments:** 12\_2019-nCoV Outbreak\_FDA SITREP\_07 February 2020.docx  
**Flag:** Flag for follow up

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Friday, February 7, 2020 6:07 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>  
**Subject:** FDA 2019-nCOV SITREP - 07 Feb 2020

Hi,

Attached for your situational awareness is the 07 February FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support.

Have a great weekend -Michael

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:52:54 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** <no subject>  
**Attachments:** updated cases/travel warnings; CIDRAP: Study of 72,000 COVID-19 patients finds 2.3% death rate; FDA 2019-nCoV SITREP - 24 Feb 2020 (b)(5) For Consideration: Draft recommendation for FDA travel policy to countries affected by COVID-19  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:52:59 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** <no subject>  
**Attachments:** CDC Confirms Possible Instance of Community Spread of COVID-19 in U.S.; FDA 2019-nCOV SITREP - 25 Feb 2020; Availability: Cleared FDA talking points for FDA IMG and AEG use; White House seeks \$1.25 billion more for coronavirus response  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:53:24 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** <no subject>  
**Attachments:** RE: COVID-19 Agency Executive Group meeting moving forward.; COVID-19 Agency Executive Group meeting moving forward.; USFK Service Member Confirmed with COVID-19; FDA 2019-nCOV SITREP - 27 Feb 2020; RE: COVID-19 Agency Executive Group meeting; of interest  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:53:40 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: FDA 2019-nCOV SITREP - 28 Feb 2020  
**Attachments:** FDA 2019-nCOV SITREP - 28 Feb 2020  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:53:55 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** <no subject>  
**Attachments:** CDC Announces Additional COVID-19 Presumptive Positive Cases; Oregon announces first, presumptive case of novel coronavirus ; Updated Draft Travel Policy; Notes from 28 FEB AEG Call  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:54:06 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** <no subject>  
**Attachments:** First Covid-19 outbreak in a U.S. nursing home raises concerns; Travel policy updates; Notes from 29 FEB AEG call; Coronavirus Updates: First Death in U.S. Confirmed in Seattle Area  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:54:50 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: Notes from 02 MAR COVID-19 Agency Executive Group Meeting  
**Attachments:** Notes from 02 MAR COVID-19 Agency Executive Group Meeting  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: amy.abernethy@fda.hhs.gov

--



---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:55:01 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: FDA 2019-nCOV SITREP - 02 March 2020  
**Attachments:** FDA 2019-nCOV SITREP - 02 March 2020  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:55:12 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: RE- FDA 2019-nCOV SITREP - 03 March 2020  
**Attachments:** RE: FDA 2019-nCOV SITREP - 03 March 2020  
**Flag:** Flag for follow up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: amy.abernethy@fda.hhs.gov

--

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/5/2020 4:55:42 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: RE- FDA 2019-nCOV SITREP - 04 March 2020  
**Attachments:** RE: FDA 2019-nCOV SITREP - 04 March 2020  
**Flag:** Follow Up

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

--

---

**From:** Lilly, Trudy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FFF918A5EAAF496EB9F98728A1B0C242-LILLYT]  
**Sent:** 3/8/2020 9:54:20 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** RE: Request to add Dr. Amy Abernethy to your distribution list

You're welcome, Amy!

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Sunday, March 8, 2020 5:18 PM  
**To:** Lilly, Trudy <Trudy.Lilly@fda.hhs.gov>  
**Subject:** Re: Request to add Dr. Amy Abernethy to your distribution list

Thank you!

---

**From:** Lilly, Trudy <Trudy.Lilly@fda.hhs.gov>  
**Sent:** Friday, March 6, 2020 3:25 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: Request to add Dr. Amy Abernethy to your distribution list

**FYI:** You're all signed up to receive Ed's daily summaries, primarily geared towards CDER but great information anyway.

---

**From:** Staffa, Edward <Edward.Staffa@fda.hhs.gov>  
**Sent:** Friday, March 6, 2020 3:23 PM  
**To:** Lilly, Trudy <Trudy.Lilly@fda.hhs.gov>  
**Subject:** RE: Request to add Dr. Amy Abernethy to your distribution list

Sure thing Trudy --- done --- she should begin receiving the summaries on Monday.

Please remind Dr. Abernethy that that these particular summaries are specifically arranged to keep CDER leadership informed and only have some agency-wide information, and rarely anything about activities unique to other centers.

---

**From:** Lilly, Trudy <Trudy.Lilly@fda.hhs.gov>  
**Sent:** Friday, March 06, 2020 2:17 PM  
**To:** Staffa, Edward <Edward.Staffa@fda.hhs.gov>  
**Subject:** Request to add Dr. Amy Abernethy to your distribution list

Hi Ed,

Can you please add Dr. Amy Abernethy to your daily clipping service? Thanks in advance!

Trudy

---

**From:** Staffa, Edward <Edward.Staffa@fda.hhs.gov>  
**Sent:** Friday, March 6, 2020 7:50 AM  
**To:** Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Temple, Robert <Robert.Temple@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Cc:** Ahadpour, Mitra <Mitra.Ahadpour@fda.hhs.gov>; Amatrudo, Kathryn <Kathryn.Amatrudo@fda.hhs.gov>; Anagnostiadis, Eleni <Eleni.Anagnostiadis@fda.hhs.gov>; Arnold, Nathan <Nathan.Arnold@fda.hhs.gov>; Ashley, Donald <Donald.Ashley@fda.hhs.gov>; Ball, Robert <Robert.Ball@fda.hhs.gov>; Baumgartner, Kristofer

<Kristofer.Baumgartner@fda.hhs.gov>; Beach, Carter <Carter.Beach@fda.hhs.gov>; Behr, Virginia L <Virginia.Behr@fda.hhs.gov>; Bennett, Carol <Carol.Bennett@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>; Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Brown, Elizabeth <Elizabeth.Brown@fda.hhs.gov>; Buckman, Paul <Paul.Buckman@fda.hhs.gov>; Buckman-Garner, ShaAvhrée <ShaAvhree.Buckman-Garner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Cannon, Patrick <Patrick.Cannon@fda.hhs.gov>; Cunningham, Courtney C. <CourtneyC.Cunningham@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; CDER Trade Press <CDERTradePress@fda.hhs.gov>; Chen, Qi <Qi.Chen@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Clark-Lynn, Sarah <Sarah.Clark-Lynn@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Cox, Lucinda <Lucinda.Cox@fda.hhs.gov>; Dal Pan, Gerald <Gerald.DalPan@fda.hhs.gov>; Defina, Matt <Matt.Defina@fda.hhs.gov>; Dermody, Colleen <Veronica.Dermody@fda.hhs.gov>; Derr, Nancy E <Nancy.Derr@fda.hhs.gov>; Echegoyen, Edwin <Edwin.Echegoyen@fda.hhs.gov>; ElZarrad, M. Khair <Mohammed.ElZarrad@fda.hhs.gov>; Falconer, Monique <Monique.Falconer@fda.hhs.gov>; Farchione, Tiffany <Tiffany.Farchione@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Fuchs, Elissa <Elissa.Fuchs@fda.hhs.gov>; Guerrier, Natasha <Natasha.Guerrier@fda.hhs.gov>; Haghpanah, Sepideh <Sepideh.Haghpanah@fda.hhs.gov>; Hennessey, Lyndsay <Lyndsay.Hennessey@fda.hhs.gov>; Huang, Sheilyn <Sheilyn.Huang@fda.hhs.gov>; Hunter, Nina L <Nina.Hunter@fda.hhs.gov>; Ikenberry, Sarah <Sarah.Ikenberry@fda.hhs.gov>; Iles, Irina \* <Irina.Iles@fda.hhs.gov>; Jackler, Karen <Karen.Jackler@fda.hhs.gov>; Jerrick, Morgan <Morgan.Liscinsky@fda.hhs.gov>; JW Direct Reports & Deputies <JWDirectReportsandDeputies@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Kim, Sarah <Sarah.Kim@fda.hhs.gov>; Kopcha, Michael <Michael.Kopcha@fda.hhs.gov>; Kornegay, Cynthia J <Cynthia.Kornegay@fda.hhs.gov>; Kremzner, Mary E <Mary.Kremzner@fda.hhs.gov>; Laine, Susan <Susan.Laine@fda.hhs.gov>; Lambert, Tu-Van <TuVan.Lambert@fda.hhs.gov>; Lappin, Brian <Brian.Lappin@fda.hhs.gov>; Lee, Tracey (FDA) <Tracey.Lee@fda.hhs.gov>; Levy, Michael (CDER) <Michael.Levy@fda.hhs.gov>; Lilly, Trudy <Trudy.Lilly@fda.hhs.gov>; Lowy, Naomi <Naomi.Lowy@fda.hhs.gov>; Margolis, Katherine <Katherine.Margolis@fda.hhs.gov>; Maynard, Janet <Janet.Maynard@fda.hhs.gov>; McCune, Susan <Susan.McCune@fda.hhs.gov>; McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Meadows, Michelle <Michelle.Meadows@fda.hhs.gov>; Menon, Ramesh <Ramesh.Menon@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Meyer, Tamra <Tamra.Meyer@fda.hhs.gov>; Moeny, David <David.Moeny@fda.hhs.gov>; OGDREQUEST <OGDREQUEST@fda.hhs.gov>; O'Grady, Jacob <Jacob.Ogrady@fda.hhs.gov>; O'Grady, Jordana <Jordana.OGrady@fda.hhs.gov>; CDER OSE OCT <CDEROSEOCT2@fda.hhs.gov>; Pattee, Suzanne <Suzanne.Pattee@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Phucas, Kristin <Kristin.Phucas@fda.hhs.gov>; Pincock, Laura <Laura.Pincock@fda.hhs.gov>; Pinheiro, Simone P <Simone.Pinheiro@fda.hhs.gov>; Pippins, Jennifer R. <Jennifer.Pippins@fda.hhs.gov>; Rausch, Paula (FDA) <Paula.Rausch@fda.hhs.gov>; Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>; Rowzee, Anne <Anne.Rowzee@fda.hhs.gov>; Ruddy, Michelle <Michelle.Ruddy@fda.hhs.gov>; Ruiz, Diane <Diane.Ruiz@fda.hhs.gov>; Cheaves, Sarita <Sarita.Cheaves@fda.hhs.gov>; Schwemer, Tawni <Tawni.Schwemer@fda.hhs.gov>; Settle, Jill <Jill.Settle@fda.hhs.gov>; Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Slack, Mary Ann <Maryann.Slack@fda.hhs.gov>; Smalls, Fallon <Fallon.Smalls@fda.hhs.gov>; Smith, Harry <Harry.Smith@fda.hhs.gov>; Sokolowska, Marta <Marta.Sokolowska@fda.hhs.gov>; Staffa, Edward <Edward.Staffa@fda.hhs.gov>; Staffa, Judy A <Judy.Staffa@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Staton, Anna <Anna.Staton@fda.hhs.gov>; Stein, Peter <Peter.Stein@fda.hhs.gov>; Temple, Robert <Robert.Temple@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Toigo, Theresa A <Theresa.Toigo@fda.hhs.gov>; Toufanian, Maryll <Maryll.Toufanian@fda.hhs.gov>; Trivedi, Aalap <Aalap.Trivedi@fda.hhs.gov>; Unger, Ellis <Ellis.Unger@fda.hhs.gov>; Unger, Monica <Monica.Unger@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Wiggins, Thelma <Thelma.Wiggins@fda.hhs.gov>; Williams, Christina <Christina.Williams@fda.hhs.gov>; Williams, Renee (Tchoulakian) <Renee.Williams2@fda.hhs.gov>; Winthrop, Sally <Sally.Winthrop@fda.hhs.gov>; Yu, Lawrence <Lawrence.Yu@fda.hhs.gov>

**Subject:** FW: The FDA News Summary for Friday, March 06, 2020

Good morning... in the clips today:

## COVID-19 Coverage (possibly more CDER/FDA specific)

**Maryland Governor Announces State's First Three Cases Of Novel Coronavirus, Declares State Of Emergency.** The Washington Post reports "Maryland Gov. Larry Hogan said Thursday that three people from Montgomery County have been diagnosed with coronavirus: a husband and wife in their 70s and a woman who is in her 50s." The governor "declared a state of emergency to speed the delivery of funding and other resources to address the virus." The three infected individuals "contracted the virus while traveling overseas and are 'in good condition,' Hogan said." The patients "are quarantined in their homes in the county, a large and affluent suburb of about 1 million people just outside Washington. The woman is not related to the couple." NPR Reuters, Fox News, The Hill, and Politico also report.

**AmeriSource Bergen Sends list of Respiratory Drugs on Backorder --- NY Post Article Suggests the Shortage is Coronavirus-Related** The New York Post reports, "On Thursday," [drug distributor] AmeriSource Bergen "sent to its pharmacists a list of respiratory medications [no link to list in article --- I cannot find the list via online search] that it's placing on back order because they are in short supply," and, the company, "flagged nebulizer solutions and two types of generic respiratory medications used for asthma and other breathing disorders." The article also says, "Drug supplier Anda Inc., meanwhile, warned its pharmacists about low levels of respiratory drugs and inhalers, as well as antibiotics, alcohol prep pads, face masks and hand sanitizers." The article quotes a pharmacist saying, "They don't tell us why it's going on back order," and that the pharmacist "suspects it has to do with supply-chain issues arising from the deadly coronavirus, because he noted, "Most of the items on the lists are things that would help someone suffering from coronavirus." The article says, "The worrisome development comes on the heels of a Feb. 22 government update about shortages of 'critical medical products' in the US due to the coronavirus outbreak."

**Opinion: Novel Coronavirus Has Exposed Europe's Fragile Dependence On Asia For Raw Generic Drug Ingredients.** Bloomberg Opinion says that Europe's "fragile dependence on Asia for raw generic drug ingredients like paracetamol" is "proving a...immediate headache" amid the novel coronavirus outbreak. The article says, "European Union health ministers are due to discuss the security of medical supplies on Friday, after warnings that the bloc faces potentially significant shortages of crucial components imported from China as the country attempts to get back to work after virus-related shutdowns." The article notes, "Over in the U.S., which has similar supply issues when it comes to China, the Food and Drug Administration has said one drug is in short supply because of the coronavirus outbreak without naming it."

**Yesterday's House Hearing on COVID-19: Legislators Reportedly Not Getting Their Questions Answered During Coronavirus Briefings With Trump Administration Officials.** CQ Roll Call reports "...lawmakers are frustrated with the pace of [COVID-19] testing availability and were emerging from frequent briefings with more questions than answers." The article says, the Trump Administration "has been unable to answer questions about how the uninsured would be covered for the testing and treatment they might need," and adds that "HHS Secretary Alex Azar recently blamed an Obama-era" FDA "regulation on diagnostic tests for slowing the private lab industry's response to the outbreak." Excerpts: --- "HHS Assistant Secretary for Preparedness and Response Robert Kadlec told a Senate panel Thursday the agency could also invoke emergency authority to pay hospitals and provide paid leave and food stamps to workers who stay home to avoid infecting others." --- "CMS Administrator Seema Verma told reporters after briefing House members that right now, tests are free to patients since they are conducted by public labs." --- "While the FDA does not oversee lab-developed tests and didn't at the time, the agency says that the last administration did require test developers to go through FDA review during an emergency, but that the Trump administration eased this requirement in the past week." --- "By the end of this week, Azar said that public health labs will have the capacity to test up to 75,000 people. Once the hospitals have tests, that capacity could grow to 400,000 or even 1.5 million by next week, Azar said. However, once the labs receive the test kits, it can take days for the tests to undergo quality control tests and be validated, according to the FDA." --- **'Nobody can tell them where to go'** State and local officials have criticized the Trump administration for the delay in accurate testing. Public health labs for weeks could not validate CDC-supplied tests. Health experts also raised alarm that the CDC's criteria when deciding whether a patient should be eligible for a test were too strict. The CDC changed the criteria as of Wednesday, so that now any doctor who is concerned that a patient might be infected can order a test, though there are still concerns about how quickly public health labs can return the results. Sen.

Patty Murray, D-Wash., said her constituents at the heart of the U.S. outbreak don't know what to do. "I'm hearing from people who want to get tested and believe they have been exposed — but nobody can tell them where to go," she said in a letter to Vice President Mike Pence, who oversees the administration's response. "the supplemental appropriations bill the House passed Wednesday did not mandate coverage of the tests. She said she expected private insurers would cover the tests."

**Coronavirus Fuels Accelerated Regulatory Process.** GenomeWeb reports, "Despite intense scrutiny and criticism of the diagnostic testing rollout in the US for the SARS-CoV-2 virus, the emergency regulatory process may actually be proceeding at a much more rapid pace than past emergencies, which did not involve newly-emerged pathogens." Commercial tests "in development to date have faced bottlenecks in test validation, but the logjam now appears to be clearing with new US Food and Drug Administration feedback and the availability of control materials."

**Co-Diagnostics Says Shares Have Soared Due To Demand For Coronavirus Test Kits.** Reuters reports Co-Diagnostics "said on Thursday demand for its coronavirus test kits had surged as the outbreak spreads and after the U.S. Food and Drug Administration (FDA) allowed labs to use tests before authorization, sending its shares up 31%." Shares "of the molecular diagnostic test maker have more than tripled since Jan. 23, when the company said it had completed designing a screening test for the new coronavirus"

#### **LabCorp Makes Coronavirus Test Available For Ordering In US.**

Reuters reports, "Diagnostics company Laboratory Corp of America Holdings said on Thursday it plans to make its test for the new coronavirus available for ordering by healthcare providers in the United States from 6 p.m. ET." The test "detects the presence of the coronavirus and is for use in patients who meet the current guidance for testing, the company said." GenomeWeb (3/5) also reports.

**Government Has Tools To Help Make Treating Coronavirus Affordable For Patients.** HuffPost reports, "Major emergencies, from natural disasters to infectious disease outbreaks, are incredibly common, so the government has a number of tools at its disposal it can utilize to help those affected." Those tools "range from cash assistance to temporary housing to help with medical needs." For example, the departments of Health and Human Services, Defense and Veterans Affairs "jointly operate the National Disaster Medical System, which has existed since 1984 to offer direct medical care and financial assistance during public emergencies."

**Progressive Democrats Push To Limit How Much Drug Makers Can Charge For Coronavirus Vaccine.** STAT reports. "Progressive Democrats are pushing to constrain how much drug makers can charge for a coronavirus vaccine." A group of lawmakers "held a press conference Thursday to pressure the Trump administration to impose price controls on any coronavirus-related treatment, and to call on their colleagues to reconsider some of the ambitious drug pricing legislation they have put forward this Congress." The press conference "came less than 24 hours after congressional appropriators rejected those same lawmakers' attempt to include similar language in the \$8.3 billion emergency funding package that is aimed at spurring the federal response to the outbreak."

**Pharma Industry Successfully Blocks Attempts To Include Price Controls Around Coronavirus Testing, Treatments.** Politico reports pharmaceutical industry lobbyists have "successfully blocked attempts this week to include language in the \$8.3 billion emergency coronavirus spending bill that would have threatened intellectual property rights for any vaccines and treatments the government decides are priced unfairly." The ability of the pharmaceutical industry "to dictate terms as Congress struggles to address the growing U.S. outbreak is another sign of the uphill battle that likely awaits any broader bipartisan drug-pricing legislation." Additionally, the provision "to bar the government from intervening when affordability concerns arise 'blows up' existing legal measures to ensure fair drug pricing, said Jamie Love, executive director at Knowledge Ecology International."

#### **Pop Up Shop Selling Coronavirus Prevention Supplies In Washington, DC.**

The AP reports Washington, DC now has a pop up shop for coronavirus prevention supplies. The AP adds, "Adilisha Patrom, owner of a co-working and event space next to Gallaudet University," carries "different models of face masks and hand sanitizer bottles in various sizes...along a stack of information sheets from the Centers for Disease Control and Prevention" inside her storefront.

**Analyst: Only A 50 Percent Chance Gilead Coronavirus Therapy, Remdesivir, Will Work.** Bloomberg reports that one of Gilead Sciences' "biggest bulls says the drugmaker's experimental therapy for coronavirus has at best a 50/50 shot at success." Developing "a treatment for the deadly virus 'remains a somewhat risky, unclear opportunity,' RBC analyst Brian Abrahams wrote in a note." While the need for medicines "sets the bar very low for Gilead's remdesivir, prior disappointments in Ebola, confounding data and limited dosing results add to risks."

## **CDER/FDA In The News --- NON COVID-19**

**FDA Urges Drug Makers To Include Older Americans In Cancer Trials.** Bloomberg Law (see attached) reports behind a paywall that drug makers "would develop better cancer treatments for elderly populations if they included more of them in their clinical trials, the FDA said Thursday in policy recommendations to improve representation for older patients." Research "shows roughly 60% of cancers occur in those 65 years of age or older." But, the FDA recommendations state: "Older adults are underrepresented in cancer clinical trials despite representing a growing segment of the population of cancer patients."

**FDA Issues Warning Letter To ADHD Drugmaker Outlook Pharmaceutical For False, Misleading Sponsored Links.** FiercePharma reports the FDA's Office of Prescription Drug Promotion has issued its "first warning letter of 2020, and it censures" ADHD drugmaker Outlook Pharmaceutical "for 'false or misleading' sponsored links on Google for ADHD med ProCentra." The paid ad "failed to include any risk information about the drug, simply positing that the med 'may be the solution you're looking for.'"

## **Other Opioid News**

## **Other COVID-19 News**

See Separate attached Word document and...

additional links below (from different sources, may overlap/duplicate)

### **Coronavirus**

- Cruise Ship With Thousands Awaits Test Results As Coronavirus Continues Spreading Around The Country
- Coronavirus Cases Surge Across U.S. As Americans Face Looming Outbreak
- Coronavirus In N.Y.: 2,773 People Are Under Quarantines In City: The Coronavirus Outbreak
- White House Sidelines Azar From Coronavirus Response
- Why Trump's Coronavirus Response Was Never Going To Work
- The Flu Has Killed Far More People Than Coronavirus. So Why All The Frenzy About COVID-19?
- States, Insurers Move To Limit Coronavirus Testing Costs For Patients
- 'It's Going To End In Death': Doctors Say U.K. Ill-Prepared For Coronavirus: The Coronavirus Outbreak
- US Does Not Have Enough Coronavirus Test Kits To Meet Demand: Pence
- If Coronavirus-Stricken China Can't Export Medicine, The World Is In Trouble
- Column: Stockpiling Sanitizer, Toilet Paper Is Understandable. But Is It Rational?
- Op-Ed: Without Universal Healthcare, Coronavirus Puts Us All At Risk
- Life In Seattle, America's Coronavirus Capital
- As Coronavirus Spreads, The Bill For Our Public Health Failures Is Due
- When Coronavirus Quarantine Is Class Warfare
- A Warning For The Next Pandemic
- The Federal Government Has Failed To Prepare For The Coronavirus
- Global Spread Of New Virus Brings More Travel Woes, Bans
- Health Care Workers Worry About Coronavirus Protection



- A Global Outbreak Is Fueling The Backlash To Globalization: The Coronavirus Outbreak
- A Dog Has A 'Low-Level' Coronavirus Infection
- WHO Racing To Send Supplies To Countries As New Virus Surges
- Italian Coronavirus Deaths Jump To 148, Cases Climb To 3,858
- Europe Could Face More Drug Shortages As Coronavirus Squeezes Supplies
- 'Almost Without Precedent': Airline Industry Hit Hard By Coronavirus: The Coronavirus Outbreak

**From:** Bulletin Intelligence <FDA@BulletinIntelligence.com>  
**Sent:** Friday, March 06, 2020 6:09 AM  
**To:** FDA@bulletinintelligence.com  
**Subject:** The FDA News Summary for Friday, March 06, 2020

This morning's FDA News Summary is attached.

**Website:** You can also read today's briefing, including searchable archive of past editions, at <http://FDA.BulletinIntelligence.com/>.

**Full-text Links:** Clicking the hypertext links in our write-ups will take you to the newspapers' original full-text articles.

**Interactive Table of Contents:** Clicking a page number on the table of contents page will take you directly to that story.

**Contractual Obligations and Copyright:** This copyrighted material is for the internal use of FDA employees only and, by contract, may not be redistributed without Bulletin Intelligence's express written consent.

**Contact Information:** Please contact us any time at 703-483-6100 or [FDA@BulletinIntelligence.com](mailto:FDA@BulletinIntelligence.com). Use of this email address will automatically result in your message being delivered to everyone involved with your service, including senior management. Thank you.

**Unsubscribe:** This copy of the FDA News Summary was sent to you because you are registered for email notification on our website. If you would like to cancel email delivery click [here](#).

---

**From:** McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]  
**Sent:** 3/11/2020 2:39:02 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]  
**Subject:** RE: FDA Heads Up for HHS NN - 3/12/19

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT CONTAINS CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

**TODAY LATE BREAKING: We are currently clearing a statement on diagnostic test supplies. Trying to get out today.**

**Press Release: Coronavirus Disease 2019 (COVID-19) update: diagnostic test supplies**

Today/tomorrow, FDA is issuing a statement on the status of diagnostics for coronavirus and materials needed to execute those tests. This statement will include FDA efforts to support labs getting online and optimizing testing availability.

---

**From:** Steele, Danielle (HHS/IOS) [Danielle.Steele@hhs.gov]  
**Sent:** 3/11/2020 5:01:52 PM  
**To:** McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]  
**Subject:** RE: FDA Heads Up for HHS NN - 3/12/19

Thank you!

**Danielle Steele**

Senior Advisor, Immediate Office of the Secretary  
U.S. Department of Health and Human Services  
600E | Direct: 202- (b)(6) (b)(6)

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Wednesday, March 11, 2020 4:59 PM  
**To:** Rebello, Heidi (FDA/OC) <Heidi.Rebello@fda.hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas (FDA/OC) <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>;

Beardsley, Sara (FDA/OC) <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Flahive, James (FDA/OC) <James.Flahive@fda.hhs.gov>; Tobias, Lindsay (FDA/OC) <Lindsay.Tobias@fda.hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>  
**Subject:** RE: FDA Heads Up for HHS NN - 3/12/19

Late addition:

**CONFIDENTIAL**

**(b)(5)**

---

**From:** McWilliams, Carly  
**Sent:** Wednesday, March 11, 2020 4:39 PM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; 'Hahn, Stephen'  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>  
**Subject:** RE: FDA Heads Up for HHS NN - 3/12/19

**UPDATED**

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT CONTAINS CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

**TODAY LATE BREAKING: We are currently clearing a statement on diagnostic test supplies. Trying to get out today.**

**(b)(5)**

**CONFIDENTIAL**

---

**From:** McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]  
**Sent:** 3/12/2020 9:05:59 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]  
**Subject:** RE: FDA Heads Up for HHS NN - 3/13/19

Updated. Lake Breaking, will go tomorrow am.

**Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA grants third Emergency Use Authorization**

Tomorrow, the FDA is taking two significant actions in the agency's ongoing and aggressive commitment to address the coronavirus outbreak (COVID19). First, the agency updated its policy/issued enforcement discretion to give New York State Department of Health (NYSDOH) the flexibility to allow laboratories authorized by the state to begin patient testing after validating their tests and notifying the NYSDOH. Laboratories will provide validation data to NYSDOH within 15 business days in lieu of an Emergency Use Authorization (EUA) to FDA. Additionally, the FDA authorized the Roche cobas® SARS-CoV-2 Test, the third Emergency Use Authorization (EUA) granted during the COVID-19 outbreak.

confidential

---

**From:** McWilliams, Carly

**Sent:** Thursday, March 12, 2020 2:28 PM

**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; 'Hahn, Stephen'

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>

**Subject:** RE: FDA Heads Up for HHS NN - 3/13/19

Tomorrow, Friday the 13<sup>th</sup>! Seems appropriate. Admiral Giroir, our team is flagging the second item for you as well given your interest in the topic.

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT CONTAINS CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

**FDA in Brief on competitive generic therapies guidance, quoting Commissioner.** Tomorrow, FDA is finalizing the guidance for industry, "Competitive Generic Therapies," which describes the process that potential ANDA applicants should follow to request designation of a drug as a competitive generic therapy (CGT) and the criteria for designating a drug as a CGT. The guidance includes information on the actions FDA may take to expedite the development and review of ANDAs for drugs designated as CGTs and provides information on a 180-day exclusivity period for certain first approved applicants that submit ANDAs for CGTs.

**CONFIDENTIAL**

**FDA issues draft guidance on slowly progressive, low-prevalence rare diseases with substrate deposition that results from single enzyme defects**

Tomorrow, FDA is issuing draft guidance will describe the evidence that should be provided to demonstrate the effectiveness of investigational drugs or new drug uses intended to treat slowly progressive, low-prevalence rare diseases associated with substrate deposition and are caused by single enzyme defects. The FDA will issue tweets on the issuance of this guidance.

**CONFIDENTIAL**

---

**From:** Schiller, Lowell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77949B06919E4F91AA788E9A616C50C7-LOWELL.SCHI]  
**Sent:** 3/16/2020 3:20:12 PM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; COVID-19 IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3d6b2d87a8447f588a44999cb6b3490-COVID-19 IM]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]  
**Subject:** RE: Corona Testing

Thanks, Anand.

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 2:34 PM  
**To:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>  
**Subject:** Re: Corona Testing

Thanks Lowell. I'll get this to the WH Taskforce

---

**From:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>  
**Date:** March 16, 2020 at 2:32:16 PM EDT  
**To:** COVID-19 IMG <COVID19IMG@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Caligui, Laura <Laura.Caligui@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>  
**Subject:** FW: Corona Testing  
**Importance:** High

All,

I received a call, and the email below, from the Food Marketing Institute (trade association for supermarkets/grocery stores). They have members who would like to offer retailer parking lots as testing sites. Can we provide them information or a point of contact?

Also, please note that FMI is hosting daily COVID-19 calls with their industry, and they have offered this forum as a way for FDA to communicate broadly with this industry, if helpful.

Best,  
Lowell

---

**From:** Peter Matz (FMI) <pmat@fmi.org>  
**Sent:** Monday, March 16, 2020 1:48 PM  
**To:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>  
**Subject:** Corona Testing  
**Importance:** High

Hi Lowell, as I mentioned, there is a lot of interest from FMI supermarket companies in particular re participating in the partnership announced over the weekend whereby COVID-19 testing will take place in certain retailer parking lots nationwide. The President mentioned Walmart, Target and others before requesting additional volunteers. We have several companies asking how they can learn more and offer their assistance. I understand there may be an MOU through HHS, but I haven't seen anything so I can't be sure. Any guidance or thoughts you may have would be greatly appreciated. Thank you!

Separately, we are hosting daily COVID-19 conference calls with our industry and we have invited other groups to join as well, so pls don't hesitate if FDA ever has any updates or would like to solicit feedback on corona-related challenges or response efforts.

Again, many thanks,  
Peter

Peter Matz  
Director, Food & Health Policy  
FMI - The Food Industry Association  
Direct 202.220.0805  
Cc: (b)(6)  
www.fmi.org



---

**From:** Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]  
**Sent:** 3/17/2020 2:19:49 PM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schil]; COVID-19 IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3d6b2d87a8447f588a44999cb6b3490-COVID-19 IM]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]  
**Subject:** RE: Corona Testing

We can connect them to our Stakeholder folks and also send info to the broader IEA.

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 2:18 PM  
**To:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>  
**Subject:** RE: Corona Testing

Hi Lowell, I sent this information to the WH the other day. They can also reach out to [William.robinson@cms.hhs.gov](mailto:William.robinson@cms.hhs.gov)

---

**From:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 2:07 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>  
**Subject:** FW: Corona Testing

Please see the follow-up question below from the supermarket trade assn. Is there any information we can provide them?

---

**From:** Peter Matz (FMI) <pmatz@fmi.org>  
**Sent:** Tuesday, March 17, 2020 1:35 PM  
**To:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>  
**Subject:** RE: Corona Testing

It seems possible the President may have jumped the gun by requesting additional retailers to volunteer at this point, which would be totally understandable given how much is going on right now and how fluid it all is. However, candidly, our retailers that are excited about the potential to help with this effort are growing uncomfortable with the lack of available information. Therefore, any info at all that could be passed along – even if preliminary/subject to change – would be greatly appreciated.

Thank you very much, again,  
Peter

---

**From:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 3:20 PM  
**To:** Peter Matz (FMI) <pmatz@fmi.org>  
**Subject:** RE: Corona Testing

Thank you, Peter. Really appreciate the outreach and offer. Will make sure this gets to the right people.

Best,  
Lowell

---

**From:** Peter Matz (FMI) <pmatz@fmi.org>  
**Sent:** Monday, March 16, 2020 1:48 PM  
**To:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>  
**Subject:** Corona Testing  
**Importance:** High

Hi Lowell, as I mentioned, there is a lot of interest from FMI supermarket companies in particular re participating in the partnership announced over the weekend whereby COVID-19 testing will take place in certain retailer parking lots nationwide. The President mentioned Walmart, Target and others before requesting additional volunteers. We have several companies asking how they can learn more and offer their assistance. I understand there may be an MOU through HHS, but I haven't seen anything so I can't be sure. Any guidance or thoughts you may have would be greatly appreciated. Thank you!

Separately, we are hosting daily COVID-19 conference calls with our industry and we have invited other groups to join as well, so pls don't hesitate if FDA ever has any updates or would like to solicit feedback on corona-related challenges or response efforts.

Again, many thanks,  
Peter

Peter Matz  
Director, Food & Health Policy  
FMI - The Food Industry Association  
Direct 202.220.0805  
Cell (b)(6)  
www.fmi.org

---

**From:** Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]  
**Sent:** 3/17/2020 3:41:39 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Lockheed, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**Subject:** RE: Reactive TPs  
**Attachments:** Reactive Responses 3.17.20.docx

An updated version is attached, containing new language on hand sanitizers, WHO, South Korea, diagnostics, and clinical trials.

We've left this in "Track Changes" so you can see the updates from one day to the next. This looks messy now because we are refining the document wholesale. Soon the edits will be far more minimal. If this is too distracting, choose the "No Markup" view on the Track Changes section of the Review tab in Word.

Thank you.

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 6:03 PM  
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** Re: Reactive TPs

Thank you. This was really helpful to read. It would be great to receive them nightly.

Take care,

Amy

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 5:02 PM

**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** Reactive TPs

Attached are the updated reactive responses. This will undergo some maintenance this week as we try to streamline and provide citations for the language. If you'd like, we will send to this group nightly.

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 1:02 PM

**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Subject:** Re: Follow up

Great - thanks

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 9:49 AM

**To:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Subject:** RE: Follow up

And I will circulate reactive tonight.

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 9:49 AM

**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Subject:** RE: Follow up

Yes, sorry about that. I am looking in Anand and Keagan too. Attached are the materials we provided yesterday to Dr. Hahn.

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 8:46 AM

**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

**Subject:** RE: Follow up

For the group, I think we had in mind the Daily WHTF talking points and the reactive document.

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Sent:** Monday, March 16, 2020 6:47 AM

**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

**Subject:** Follow up

Hi Friends,

I wanted to check in after our meeting/call last Wed. You mentioned sending me nightly "homework" that summarizes the evolving talking points and details. Can you add me to the distribution list so that I can familiarize myself and be as ready as possible for whenever you need me?

Thanks and take care,

Amy

---

**From:** Ramsey Kilani [ramsey@gsis.us]  
**Sent:** 3/19/2020 1:40:42 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Re: COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit Inquiry

Thank you, Amy and Anand.

Ramsey

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Thursday, March 19, 2020 11:13 AM  
**To:** Ramsey Kilani <ramsey@gsis.us>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit Inquiry

Thank you very much for your email, Ramsey.  
I am cc'ing Anand Shah here. Anand will help to steward the request to the right part of the Agency.  
Please take care,  
Amy

---

**From:** Ramsey Kilani <ramsey@gsis.us>  
**Sent:** Thursday, March 19, 2020 9:21 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit Inquiry

Dear Dr. Abernethy,

I am inquiring about the status of the registered COVID-19(SARS-CoV-2) IgM/IgG Antibody Test Kit (link below):

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRRL/rl.cfm?lid=650355&lpd=QJR>

The product code is listed as (b)(4) which indicates that it has/will not receive a device classification due to it being in EUA (Emergency Use Authorization)status (Link below):

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3674>

My specific questions are:

Is this device considered FDA-approved (temporary or otherwise) for COVID-19 Antibody detection given its EUA designation?

Can this device be used now in the U.S. or must it first be classified? If no, will this device be formally classified while in EUA status?

## Product Classification - Food and Drug Administration

Device: reagents, 2019-novel coronavirus nucleic acid: Definition: Nucleic acid-based in vitro diagnostic devices for the detection of 2019-novel coronavirus (2019-nCoV) and/or diagnosis of 2019-nCoV infection in human clinical specimens.

[www.accessdata.fda.gov](http://www.accessdata.fda.gov)

Thank you in advance for taking time to review this inquiry.

Best Regards,

**Ramsey Kilani, M.D.**

Chief Medical Officer

Global Security and Innovative Strategies

[ramsey@gsis.us](mailto:ramsey@gsis.us)

O: +1.202.888.2360

M: +1. (b)(6)

[www.gsis.us](http://www.gsis.us)



---

**From:** McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]  
**Sent:** 3/19/2020 10:31:50 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**Subject:** Summary for tomorrow  
**Attachments:** 2020.03.19 Summary.docx

Hi, attached is a one pager on most significant items today and tomorrow.

Thanks all,

Carly



---

**From:** Moore, Rhonda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3EDB017DAC98417CAEAD9EA79795CCBD-RHONDA.MOOR]  
**Sent:** 3/20/2020 2:06:38 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** re: interesting paper on Candidate Drugs/COVID  
**Attachments:** Homology\_Modeling\_of\_TMPRSS2\_Yields\_Candidate\_Drugs\_That\_May\_Inhibit\_Entry\_of\_SARS-CoV-2\_into\_Human\_Cells\_v1.pdf

Hat tip to Russ Altman for sending this on –of interest 😊 Peace and be well, Rhonda

Rhonda J. Moore, PhD, FRSA

Social Scientist

P: 301-796-2150; C: (b)(6)

Email: [Rhonda.Moore@fda.hhs.gov](mailto:Rhonda.Moore@fda.hhs.gov)

...Imagine what our real neighborhoods would be like if each of us offered, as a matter of course, just one kind word to another person....

--From Mr. Roger's Neighborhood

---

**From:** Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]  
**Sent:** 3/20/2020 6:00:49 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Lockeed, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Luebke, Yasemin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]  
**Subject:** Reactive TPs  
**Attachments:** Reactive Responses 3.20.20.docx

Attached is the latest version of the Reactive Talking Points.

Amy, Anand, or Keagan or Carly for the Commissioner, (or anyone), please let us know if there are areas you'd like to see added or revised.

Thank you and hope you have a restful weekend.

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/21/2020 12:58:27 PM  
**To:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Re: FYI - Fauci

Thank you, Michael.

Yes, please keep me looped in on these going forward.

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Saturday, March 21, 2020 11:47 AM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** RE: FYI - Fauci

+Amy who is working on this as well.

This is the response that CDER was comfortable with. I'll share with OCC but this seems pretty generic.

(b)(5)

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Date:** March 20, 2020 at 7:39:04 PM EDT  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Caligui, Laura <Laura.Caligui@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: FYI - Fauci

(b)(5)

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 7:34 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: FYI - Fauci

I think if asked, we'll need to say something like the following, if asked about this: (b)(5)

(b)(5)

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 7:27 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Cc:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: FYI - Fauci

Haven't heard anything about this concept: (b)(5)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 7:21 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** Re: FYI - Fauci

Anand?

Sent from my iPhone

On Mar 20, 2020, at 7:13 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

On CBS Evening News:

"I was just speaking to the Commissioner of FDA, together with Dr. Birx, about having an online system where people can actually get on and have a doctor make the determination whether or not they should be put on (hydroxychloroquine) but also have the capability of collecting information."

I'm not familiar with what he's talking about, but I'm sure we're going to have to (at some point) provide more detail – and since he mentioned it publicly, likely before we're able to roll out something larger.

Michael  
**Michael Felberbaum**  
*Senior Advisor*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-9548 / Cell: (b)(6)  
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/21/2020 6:55:37 PM  
**To:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Fw: CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT

FYI

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Saturday, March 21, 2020 6:55 PM  
**To:** Agus, David <agus@med.usc.edu>  
**Subject:** Re: CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT

It also speaks to the need to be able to have the platform get continuously updated with the latest guidelines - which, as we both know, is a great use of tech platforms.

---

**From:** Agus, David <agus@med.usc.edu>  
**Sent:** Saturday, March 21, 2020 6:48 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT

Wild. . .  
Means empirically treating

---

**From:** "Giraldo, Luis" <GiraldoL@cbsnews.com>  
**Date:** Saturday, March 21, 2020 at 3:47 PM  
**To:** "@CND Corona Virus" <CNDCoronaVirus@cbsnews.com>  
**Cc:** "Hsu, Anne" <hsua@cbsnews.com>  
**Subject:** CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT  
**Resent-From:** David Agus <agus@usc.edu>  
**Resent-Date:** Saturday, March 21, 2020 at 3:47 PM

Hi all, below is a an article flagged by Anne Hsu on a specific set of guidance sent to healthcare workers about a shift in testing priorities.

We were able to find the press release referenced below where public health officials advise doctors not to test those only experiencing mild respiratory symptoms.

RELEASE: <http://publichealth.lacounty.gov/eprp/lahan/alerts/LAHANCOVID031920.pdf>

TRANSCRIPT (BOTTOM OF SECOND PAGE):

### Recommendations

#### Testing

- COVID-19 testing at PHL is preferred for persons meeting the following criteria because a timely result can inform an urgent public health response:

**Unless confirming a diagnosis of COVID-19 will impact patient management, DPH strongly recommends against COVID-19 diagnostic testing for persons with mild febrile respiratory illness who can be safely managed at home. This will minimize possible exposures to healthcare workers, patients, and the public and will reduce the demand for personal protective equipment.**

**• It is recommended that providers test only persons with symptoms compatible with COVID-19 where a diagnostic result will change clinical management or inform public health response.**

- Testing of asymptomatic persons is not recommended because the available tests have not been approved and validated for testing of those without symptoms. If patients know they have been exposed, they should be counseled to self-quarantine. Isolation and Quarantine
- Patients with confirmed COVID-19 should be provided with home isolation instructions.
- Patients who are waiting for COVID-19 test results should be presumed infectious and instructed to follow home isolation instructions.
- Persons with mild febrile respiratory illness in whom diagnostic testing will not change management should be presumed to have COVID-19. They should be instructed to isolate themselves and follow home care instructions.
- Close contacts (household members, intimate partners, and caregivers) to a person with suspected or confirmed COVID-19 should be provided with home quarantine instructions.

Best,

Luis

(THANK YOU ANNE AND FTN FOR FLAGGING)

---

Health officials in New York City and Los Angeles County are signaling a change in local strategy when it comes to coronavirus testing, recommending that doctors avoid testing patients except in cases where a test result would significantly change the course of treatment.

**A news release from the Los Angeles Department of Public Health this week advised doctors not to test those experiencing only mild respiratory symptoms unless “a diagnostic result will change clinical management or inform public health response.”**

The recommendation reflects a "shifting from a strategy of case containment to slowing disease transmission and averting excess morbidity and mortality," according to the statement.

The guidance said coronavirus testing at L.A. County public health labs will prioritize those with symptoms, health care workers, residents of long-term care facilities, paramedics and other high-risk situations. Others are encouraged to simply stay at home.

At about the same time, the New York City Department of Health directed all healthcare facilities to immediately stop testing non-hospitalized patients for Covid-19.

“At this point in the pandemic, demand for unnecessary testing is contributing to the rapidly diminishing supply of PPE and leading to a decreasing supply of swabs and viral transport media used to collect diagnostic specimens for Covid-19 testing,” a statement read. “Testing may play a more significant role after the pandemic has peaked.”

**Some context:** The strategy shift essentially codifies the reality health departments have been living with for weeks; a shortage of tests and protective equipment amid rising demand and case numbers.

It also puts into practice advice from many of America’s top medical experts, including CNN’s Dr. Sanjay Gupta, that a positive test result is not required to treat the symptoms.

Naturally, limiting testing in America’s two largest population centers would also likely lead to widespread under-counting of total cases.

Here’s the CNN article:

[https://www.cnn.com/world/live-news/coronavirus-outbreak-03-21-20-intl-hnk/h\\_78c431662464112a27434663a0860cdc](https://www.cnn.com/world/live-news/coronavirus-outbreak-03-21-20-intl-hnk/h_78c431662464112a27434663a0860cdc)

-----

Anne Hsu

Senior Producer, FACE THE NATION

[c] 646-935-9270

[o] 202-457-1597




---

**From:** Berrellez, Jessica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFAA6CC191F447659C6AB592B78F4AF4-JESSICA.BER]  
**Sent:** 3/22/2020 10:32:13 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Weekly Activities  
**Attachments:** TechMap-storyboards-Mar20.pdf; CoV Outbreak\_FDA SITREP\_V2.3.docx

<!--[if lte mso 15 || CheckWebRef]-->

Berrellez, Jessica has shared a OneDrive for Business file with you. To view it, click the link below.

 Datavant Brainstorm Ideas.docx

<!--[endif]-->

Hi Amy,

I hope you had a great weekend. Below please find my list of updates.

Thanks,

Jess

**(b)(5)**

**(b)(5)**

Best,

Jess

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 3/22/2020 10:43:21 PM  
**To:** McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]  
**CC:** Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**Subject:** RE: WHTF meeting background 3/23  
**Attachments:** 2020.03.23 Background from WH Task Force Meeting final.docx

Thanks Carly – one edit re: ventilator guidance.

Best,

Denise

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Sunday, March 22, 2020 10:31 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Cc:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Subject:** WHTF meeting background 3/23

Please see attached.

---

**From:** Hoffman, Allison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEED30BE6A004DD29AC6C7F8EBCADBC5-ALLISON.HOF]  
**Sent:** 3/23/2020 7:47:23 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]  
**Subject:** Meeting prep for NASEM Mar 24 2020 and WSJ Mar 24 2020  
**Attachments:** Meeting prep sheet NASEM Mar 24 2020.docx; Meeting prep sheet WSJ Health Forum Mar 24 2020.docx

Hi Amy,

Your meeting prep for tomorrow's (March 24, 2020) virtual meetings w/ NASEM and the WSJ are attached. You are receiving the latest reactive TPs re: the coronavirus/COVID19 directly from Andy Tantillo so you will always have the most recent version of reactive talkingpoints. However, OMA sent the one from Friday to me, so it's included in the WSJ packet. I've noted that the drug development and vaccine reactive TPs are on pages 16-20.

Allison

---

**From:** Agus, David [agus@med.usc.edu]  
**Sent:** 3/23/2020 8:36:41 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Re: [External] Re: CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT

Checking in. . .

---

**From:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Date:** Saturday, March 21, 2020 at 3:55 PM  
**To:** "Agus, David" <agus@med.usc.edu>  
**Subject:** [External] Re: CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT

It also speaks to the need to be able to have the platform get continuously updated with the latest guidelines - which, as we both know, is a great use of tech platforms.

---

**From:** Agus, David <agus@med.usc.edu>  
**Sent:** Saturday, March 21, 2020 6:48 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT

Wild. . .  
Means empirically treating

---

**From:** "Giraldo, Luis" <GiraldoL@cbsnews.com>  
**Date:** Saturday, March 21, 2020 at 3:47 PM  
**To:** "@CND Corona Virus" <CNDCoronaVirus@cbsnews.com>  
**Cc:** "Hsu, Anne" <hsua@cbsnews.com>  
**Subject:** CONFIRMED: LA COUNTY TESTING PRIORITIES SHIFT  
**Resent-From:** David Agus <agus@usc.edu>  
**Resent-Date:** Saturday, March 21, 2020 at 3:47 PM

Hi all, below is a an article flagged by Anne Hsu on a specific set of guidance sent to healthcare workers about a shift in testing priorities.

We were able to find the press release referenced below where public health officials advise doctors not to test those only experiencing mild respiratory symptoms.

RELEASE: <http://publichealth.lacounty.gov/eprp/lahan/alerts/LAHANCOVID031920.pdf>

TRANSCRIPT (BOTTOM OF SECOND PAGE):

### Recommendations

#### Testing

- COVID-19 testing at PHL is preferred for persons meeting the following criteria because a timely result can inform an urgent public health response:

**Unless confirming a diagnosis of COVID-19 will impact patient management, DPH strongly recommends against COVID-19 diagnostic testing for persons with mild febrile respiratory illness who can be safely managed at home. This will minimize possible exposures to healthcare workers, patients, and the public and will reduce the demand for personal protective equipment.**

**• It is recommended that providers test only persons with symptoms compatible with COVID-19 where a diagnostic result will change clinical management or inform public health response.**

- Testing of asymptomatic persons is not recommended because the available tests have not been approved and validated for testing of those without symptoms. If patients know they have been exposed, they should be counseled to self-quarantine. Isolation and Quarantine
- Patients with confirmed COVID-19 should be provided with home isolation instructions.
- Patients who are waiting for COVID-19 test results should be presumed infectious and instructed to follow home isolation instructions.
- Persons with mild febrile respiratory illness in whom diagnostic testing will not change management should be presumed to have COVID-19. They should be instructed to isolate themselves and follow home care instructions.
- Close contacts (household members, intimate partners, and caregivers) to a person with suspected or confirmed COVID-19 should be provided with home quarantine instructions.

Best,

Luis

(THANK YOU ANNE AND FTN FOR FLAGGING)

---

Health officials in New York City and Los Angeles County are signaling a change in local strategy when it comes to coronavirus testing, recommending that doctors avoid testing patients except in cases where a test result would significantly change the course of treatment.

**A news release from the Los Angeles Department of Public Health this week advised doctors not to test those experiencing only mild respiratory symptoms unless “a diagnostic result will change clinical management or inform public health response.”**

The recommendation reflects a "shifting from a strategy of case containment to slowing disease transmission and averting excess morbidity and mortality," according to the statement.

The guidance said coronavirus testing at L.A. County public health labs will prioritize those with symptoms, health care workers, residents of long-term care facilities, paramedics and other high-risk situations. Others are encouraged to simply stay at home.

At about the same time, the New York City Department of Health directed all healthcare facilities to immediately stop testing non-hospitalized patients for Covid-19.

“At this point in the pandemic, demand for unnecessary testing is contributing to the rapidly diminishing supply of PPE and leading to a decreasing supply of swabs and viral transport media used to collect diagnostic specimens for Covid-19 testing,” a statement read. “Testing may play a more significant role after the pandemic has peaked.”

**Some context:** The strategy shift essentially codifies the reality health departments have been living with for weeks; a shortage of tests and protective equipment amid rising demand and case numbers.

It also puts into practice advice from many of America’s top medical experts, including CNN’s Dr. Sanjay Gupta, that a positive test result is not required to treat the symptoms.

Naturally, limiting testing in America’s two largest population centers would also likely lead to widespread under-counting of total cases.

Here’s the CNN article:

[https://www.cnn.com/world/live-news/coronavirus-outbreak-03-21-20-intl-hnk/h\\_78c431662464112a27434663a0860cdc](https://www.cnn.com/world/live-news/coronavirus-outbreak-03-21-20-intl-hnk/h_78c431662464112a27434663a0860cdc)

-----

Anne Hsu

Senior Producer, FACE THE NATION

[c] 646-935-9270

[o] 202-457-1597

---

**From:** Hunter, Nina L [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8005F93BD66A4DFC83EBDAA67D9FD33B-NLH]  
**Sent:** 3/23/2020 2:49:35 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Maynard, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cab5888ca99495880d8220c67476f8e-MAYNARDJ]  
**Subject:** FW: DRU-2020-7390 signed letter  
**Attachments:** 20-7390\_DESLtr.3.19.20 JM.pdf

Hi Amy, Sharing for awareness.

---

**From:** Maynard, Janet <Janet.Maynard@fda.hhs.gov>  
**Sent:** Monday, March 23, 2020 2:38 PM  
**To:** Hunter, Nina L <Nina.Hunter@fda.hhs.gov>  
**Subject:** FW: DRU-2020-7390 signed letter

We are sending the designation letter for remdesivir for COVID 19. Thank you, Janet



---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 3/25/2020 6:24:28 AM  
**To:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]  
**CC:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Subject:** Re: FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

For visibility, here is the NYT article about it.

<https://www.nytimes.com/2020/03/24/us/politics/trump-oracle-coronavirus-chloroquine.html?searchResultPosition=1>



## Oracle Providing White House With Software to Study Unproven Coronavirus Drugs

The online platform could allow physicians to upload patient data on how malaria drugs perform on coronavirus patients.

[www.nytimes.com](http://www.nytimes.com)

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 11:25 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

[https://www.washingtonpost.com/politics/oracle-to-partner-with-trump-administration-to-collect-data-on-use-of-antimalarial-drugs-to-treat-covid-19/2020/03/24/ecbb8b76-6de2-11ea-b148-e4ce3fbd85b5\\_story.html](https://www.washingtonpost.com/politics/oracle-to-partner-with-trump-administration-to-collect-data-on-use-of-antimalarial-drugs-to-treat-covid-19/2020/03/24/ecbb8b76-6de2-11ea-b148-e4ce3fbd85b5_story.html)

# Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19

A series of conversations President Trump has had with tech billionaire Larry Ellison have helped convince him that two old anti-malarial drugs may be game-changing treatments for covid-19, the disease caused by the novel coronavirus, according to four people familiar with the conversations.

Trump has said he has “a good feeling” about the drugs based on anecdotal reports, even though there is scant data showing they benefit people with covid-19. Now, Ellison — who recently held a high-profile fundraiser for Trump — has helped arrange a partnership between Oracle, the software company he co-founded, and the federal government to crowdsource that idea by collecting data in real time from doctors trying out those and other unproven drugs on covid-19 patients.

While the anti-malarial drugs are also being tested in clinical trials, the primary purpose of Oracle’s new website and mobile app is to help gather information on patients prescribed the medications outside of trials and more quickly assess whether the drugs — or any others that may emerge as possible treatments — are effective against covid-19, for which there is no proven treatment. The company plans to donate the site to the government.

Chloroquine and hydroxychloroquine are approved for malaria, so doctors can prescribe them for other illnesses. Some are trying them on patients with covid-19 based on anecdotal reports that they are sometimes helpful. The Oracle technology is meant to help the government collect data “in real time” and faster than in traditional Food and Drug Administration clinical trials, said one person familiar with the discussions, who spoke on the condition of anonymity because he was not authorized to speak publicly.

Oracle declined requests to comment for this story.

The administration is also exploring whether it will offer bonus payments to doctors who use the technology. This raises ethical concerns among some health officials, who fear that will further promote the use of unproven drugs, according to a person familiar with the plans, who also spoke on the condition of anonymity because he was not authorized to share the conversations. Some of the president’s top health officials have urged the government to proceed with randomized clinical trials to ensure they have definitive data about what does and does not work, several senior administration officials said.

The White House did not respond to multiple requests for comment.

Trump’s conversations with Ellison have played a significant role in the president’s recent statements during daily White House coronavirus briefings and on Twitter pushing the anti-malarials, according to four people familiar with the conversations, who spoke on the condition of anonymity because they were not authorized to share them.

The president's recent statements underscore his desire for a quick fix to the rapidly escalating pandemic that has infected more than 53,000 Americans and killed upward of 600. They have also resulted in shortages of chloroquine and hydroxychloroquine for patients who need them for other uses. Even in private, the president has dismissed concerns from doctors that the drugs are not adequately tested, saying it is a dire situation and he wants people to have options, say senior officials.

Last week, shortly after Trump's initial conversations with Ellison, he convened several top health officials and aides in an Oval Office meeting to discuss whether the government could expedite approval of chloroquine, hydroxychloroquine and remdesivir, an antiviral that has not been approved for any use but is currently being scrutinized in several late-stage trials.

The meeting included FDA Commissioner Stephen Hahn, Centers for Disease Control and Prevention Director Robert Redfield and Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, among others, according to people familiar with the gathering.

The officials pushed back on the idea, urging the president to wait for the results of randomized clinical trials that meet the FDA's standards.

But Health and Human Services Secretary Alex Azar, who had been asked by Trump earlier that day to find legal authority to immediately approve the drugs, told the president he had conferred with his lawyers and had options for immediate approval if Trump wanted them, including emergency authorities granted to the health secretary.

A senior administration official said Azar was not advocating for immediate approval but presenting the president with options he had requested.

The other officials in the room were stunned at the suggestion and urged Trump to rely on the clinical trials.

Trump ultimately stood down, but still turned to Ellison and Oracle to build a website to collect data on the drugs' efficacy outside of official clinical trials, and he has continued to push the drugs as possible treatments in daily briefings.

Ellison is heavily involved in health care, in addition to software. He launched a wellness company called Sensei and is a major shareholder in Quark Pharmaceuticals, which develops therapeutics based on gene discovery. He also funded a cancer institute at the University of Southern California led by Los Angeles doctor David Agus, who has been involved in discussions with the administration.

Joshua Sharfstein, vice dean for public health practice and community engagement at the Johns Hopkins Bloomberg School of Public Health, said he had heard few details about the Oracle website but was unenthusiastic based on what he knew.

"It sounds like a very poor substitute for a well-designed clinical trial," said Sharfstein, who was FDA deputy commissioner during the Obama administration. He added that a trial could be conducted quickly without a large number of patients.

The fastest, best way to know whether something works is to randomly assign patients to treatments and then see what happens, he said. “Otherwise, it’s hard to know whether something works.”

Trump has repeatedly talked up the malaria drugs from the White House podium. He has cited a small study of 36 patients in France that administered chloroquine and an antibiotic called azithromycin. “HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine,” Trump tweeted Saturday.

“I feel like I feel, as the expression goes, what do we have to lose? Because, you know, I feel very, I feel very good about it,” Trump said during a White House briefing Saturday.

Fauci interjected to say the president was right to have hope, but he urged caution in placing too much faith in the drugs without proper data.

“Many of the things that you hear out there are what I had called anecdotal reports. They may be true, but they’re anecdotal,” Fauci said. “So the only thing that I was saying is that if you really want definitively to know if something works, that you’ve got to do the kind of trial that you get, the good information. The president is talking about hope for people. And it’s not an unreasonable thing to hope for people.”

Medical and health experts have raised concerns that the president is pushing unproven treatments, leading people to try to obtain the drug. After hearing the president’s remarks, an Arizona man ingested chloroquine phosphate, a fish tank cleaner, in an effort to prevent covid-19, and died shortly after. His wife also ingested the substance and has been hospitalized.

“When the president comes in and says that he has a feeling that something is going to work very well, he makes it much harder to do that science,” said Ashish Jha, a professor at Harvard University and director of the Harvard Global Health Institute. “He makes it much harder for us to learn and figure out which treatments are going to work.”

On Tuesday, the state of New York was scheduled to begin testing chloroquine and hydroxychloroquine as treatments for covid-19.

---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 3/25/2020 8:20:10 AM  
**To:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Subject:** Re: FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

Yes, that is correct. Thanks, Michael

Sent from my iPhone

On Mar 25, 2020, at 8:10 AM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Thank you. Assuming we don't have anything we can share with reporters at this moment beyond what we cleared previously, which is:

We are actively working with our federal health partners as well as academic medical centers on the COVID-19 response and collecting data in a variety of ways about potential therapies. We will share additional information when available.

**Michael Felberbaum**

*Senior Advisor*

**Office of Media Affairs**

**Office of External Affairs**

**U.S. Food and Drug Administration**

Tel: 240-402-9548 / Cell: (b)(6)

michael.felberbaum@fda.hhs.gov

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Date:** March 25, 2020 at 6:24:30 AM EDT

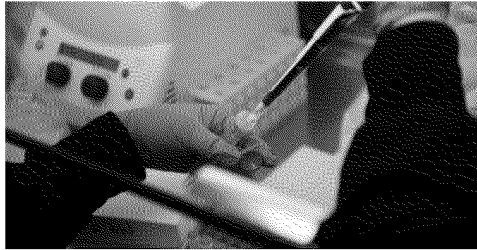
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>

**Cc:** Caligui, Laura <Laura.Caligui@fda.hhs.gov>, Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

**Subject:** Re: FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

For visibility, here is the NYT article about it.

<https://www.nytimes.com/2020/03/24/us/politics/trump-oracle-coronavirus-chloroquine.html?searchResultPosition=1>



## Oracle Providing White House With Software to Study Unproven Coronavirus Drugs

The online platform could allow physicians to upload patient data on how malaria drugs perform on coronavirus patients.

[www.nytimes.com](http://www.nytimes.com)

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

**Sent:** Tuesday, March 24, 2020 11:25 PM

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

**Subject:** FYI: Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19 - The Washington Post

[https://www.washingtonpost.com/politics/oracle-to-partner-with-trump-administration-to-collect-data-on-use-of-antimalarial-drugs-to-treat-covid-19/2020/03/24/ecbb8b76-6de2-11ea-b148-e4ce3fbd85b5\\_story.html](https://www.washingtonpost.com/politics/oracle-to-partner-with-trump-administration-to-collect-data-on-use-of-antimalarial-drugs-to-treat-covid-19/2020/03/24/ecbb8b76-6de2-11ea-b148-e4ce3fbd85b5_story.html)

# Oracle to partner with Trump administration to collect data on unproven drugs to treat covid-19

A series of conversations President Trump has had with tech billionaire Larry Ellison have helped convince him that two old anti-malarial drugs may be game-changing treatments for covid-19, the disease caused by the novel coronavirus, according to four people familiar with the conversations.

Trump has said he has “a good feeling” about the drugs based on anecdotal reports, even though there is scant data showing they benefit people with covid-19. Now, Ellison — who recently held a high-profile fundraiser for Trump — has helped arrange a partnership between Oracle, the software company he co-founded, and the federal government to

crowdsource that idea by collecting data in real time from doctors trying out those and other unproven drugs on covid-19 patients.

While the anti-malarial drugs are also being tested in clinical trials, the primary purpose of Oracle's new website and mobile app is to help gather information on patients prescribed the medications outside of trials and more quickly assess whether the drugs — or any others that may emerge as possible treatments — are effective against covid-19, for which there is no proven treatment. The company plans to donate the site to the government.

Chloroquine and hydroxychloroquine are approved for malaria, so doctors can prescribe them for other illnesses. Some are trying them on patients with covid-19 based on anecdotal reports that they are sometimes helpful. The Oracle technology is meant to help the government collect data "in real time" and faster than in traditional Food and Drug Administration clinical trials, said one person familiar with the discussions, who spoke on the condition of anonymity because he was not authorized to speak publicly.

Oracle declined requests to comment for this story.

The administration is also exploring whether it will offer bonus payments to doctors who use the technology. This raises ethical concerns among some health officials, who fear that will further promote the use of unproven drugs, according to a person familiar with the plans, who also spoke on the condition of anonymity because he was not authorized to share the conversations. Some of the president's top health officials have urged the government to proceed with randomized clinical trials to ensure they have definitive data about what does and does not work, several senior administration officials said.

The White House did not respond to multiple requests for comment.

Trump's conversations with Ellison have played a significant role in the president's recent statements during daily White House coronavirus briefings and on Twitter pushing the anti-malarials, according to four people familiar with the conversations, who spoke on the condition of anonymity because they were not authorized to share them.

The president's recent statements underscore his desire for a quick fix to the rapidly escalating pandemic that has infected more than 53,000 Americans and killed upward of 600. They have also resulted in shortages of chloroquine and hydroxychloroquine for patients who need them for other uses. Even in private, the president has dismissed concerns from doctors that the drugs are not adequately tested, saying it is a dire situation and he wants people to have options, say senior officials.

Last week, shortly after Trump's initial conversations with Ellison, he convened several top health officials and aides in an Oval Office meeting to discuss whether the government could expedite approval of chloroquine, hydroxychloroquine and remdesivir, an antiviral that has not been approved for any use but is currently being scrutinized in several late-stage trials.

The meeting included FDA Commissioner Stephen Hahn, Centers for Disease Control and Prevention Director Robert Redfield and Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, among others, according to people familiar with the gathering.

The officials pushed back on the idea, urging the president to wait for the results of randomized clinical trials that meet the FDA's standards.

But Health and Human Services Secretary Alex Azar, who had been asked by Trump earlier that day to find legal authority to immediately approve the drugs, told the president he had conferred with his lawyers and had options for immediate approval if Trump wanted them, including emergency authorities granted to the health secretary.

A senior administration official said Azar was not advocating for immediate approval but presenting the president with options he had requested.

The other officials in the room were stunned at the suggestion and urged Trump to rely on the clinical trials.

Trump ultimately stood down, but still turned to Ellison and Oracle to build a website to collect data on the drugs' efficacy outside of official clinical trials, and he has continued to push the drugs as possible treatments in daily briefings.

Ellison is heavily involved in health care, in addition to software. He launched a wellness company called Sensei and is a major shareholder in Quark Pharmaceuticals, which develops therapeutics based on gene discovery. He also funded a cancer institute at the University of Southern California led by Los Angeles doctor David Agus, who has been involved in discussions with the administration.

Joshua Sharfstein, vice dean for public health practice and community engagement at the Johns Hopkins Bloomberg School of Public Health, said he had heard few details about the Oracle website but was unenthused based on what he knew.

"It sounds like a very poor substitute for a well-designed clinical trial," said Sharfstein, who was FDA deputy commissioner during the Obama administration. He added that a trial could be conducted quickly without a large number of patients.

The fastest, best way to know whether something works is to randomly assign patients to treatments and then see what happens, he said. "Otherwise, it's hard to know whether something works."

Trump has repeatedly talked up the malaria drugs from the White House podium. He has cited a small study of 36 patients in France that administered chloroquine and an antibiotic called azithromycin. "HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine," Trump tweeted Saturday.



“I feel like I feel, as the expression goes, what do we have to lose? Because, you know, I feel very, I feel very good about it,” Trump said during a White House briefing Saturday.

Fauci interjected to say the president was right to have hope, but he urged caution in placing too much faith in the drugs without proper data.

“Many of the things that you hear out there are what I had called anecdotal reports. They may be true, but they’re anecdotal,” Fauci said. “So the only thing that I was saying is that if you really want definitively to know if something works, that you’ve got to do the kind of trial that you get, the good information. The president is talking about hope for people. And it’s not an unreasonable thing to hope for people.”

Medical and health experts have raised concerns that the president is pushing unproven treatments, leading people to try to obtain the drug. After hearing the president’s remarks, an Arizona man ingested chloroquine phosphate, a fish tank cleaner, in an effort to prevent covid-19, and died shortly after. His wife also ingested the substance and has been hospitalized.

“When the president comes in and says that he has a feeling that something is going to work very well, he makes it much harder to do that science,” said Ashish Jha, a professor at Harvard University and director of the Harvard Global Health Institute. “He makes it much harder for us to learn and figure out which treatments are going to work.”

On Tuesday, the state of New York was scheduled to begin testing chloroquine and hydroxychloroquine as treatments for covid-19.

---

**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 3/25/2020 12:31:28 PM  
**To:** McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** RE: REQUEST: Talkers on analysis and india lock down

Later today or tomorrow (more likely)

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 12:25 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** RE: REQUEST: Talkers on analysis and india lock down

Okay, thank you. Do we know when this will be issued?

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 12:19 PM  
**To:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** RE: REQUEST: Talkers on analysis and india lock down

We have language that CDER cleared:

There is a significant surge in demand of chloroquine/hydroxychloroquine and we are doing everything possible to work with manufacturers to increase production. We are working with manufacturers to assess their supplies and are actively evaluating market demand for patients dependent on it for treatment of malaria, lupus and rheumatoid arthritis. But please know this is a fluctuating and dynamic situation we are actively engaged on.

We are also including work with CVS and other stakeholders on this topic in a statement that is in clearance.

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 12:17 PM  
**To:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: REQUEST: Talkers on analysis and india lock down

I put in this request to cder. We are going to need to get some kind of hold language as media has already started picking up on people not being able to access chloroquine for their condition and having to pay a higher price for another drug. This was reported even before the india shut down.

# Trump Touted Chloroquine As A Possible Coronavirus Treatment. Now She Can't Find The Drug For Her Autoimmune Disease.

"I was told that not only was there none available anywhere, but they didn't know when they were going to get any more," she told BuzzFeed News.

By Salvador Hernandez



**Salvador Hernandez** BuzzFeed News Reporter

Posted on March 24, 2020, at 5:13 p.m. ET

- [Tweet](#)
- [Share](#)
- [Copy](#)



John Moore / Getty Images

A nurse prepares to give a coronavirus swab test at a drive-through testing station on Tuesday in Stamford, Connecticut.

*The journalists at BuzzFeed News are proud to bring you trustworthy and relevant reporting about the coronavirus. To help keep this news free, become a member and sign up for our newsletter, Outbreak Today.*

When she doesn't take two small tablets of hydroxychloroquine every day, the pain and fatigue of Sharon Greenstein's autoimmune disease become too much to do even the basic things of daily life.

"I can't function," she told BuzzFeed News. "I can't work. I can't do daily activities. I feel pretty sick."

About 25 years ago, Greenstein was diagnosed with Sjögren's syndrome, a disease where the immune system attacks its own body. Since then, she's been prescribed hydroxychloroquine, a drug that's also been used to treat malaria, lupus, and rheumatoid arthritis.

But after President Donald Trump announced last week that the drug could be a "game-changer" as a treatment for COVID-19, the disease caused by the coronavirus, a surge of demand hit pharmacies and manufacturers. Reports of people purchasing the drug and other products containing chloroquine to self-medicate began to surface, including a Phoenix man who died after he took a version used for fish tanks. (The use of chloroquine to treat COVID-19 continues to be studied, and doctors are recommending no one use it in any form to self-medicate.)

When Greenstein, who lives in California's Bay Area, went to her local pharmacy Friday to renew her prescription, she was told she wouldn't be able to get her refill until Monday. When she called Monday, she was told they wouldn't be able to fill her prescription at all.

"I was told that not only was there none available anywhere, but they didn't know when they were going to get any more," she said.

On Monday, the FDA told BuzzFeed News it was working with manufacturers to look at their supplies of the drug and the demand from patients who rely on it. It's still unclear when more of the drug will

become available for patients like Greenstein.

After speaking with her pharmacy on Monday, she said the only option she had was to purchase a bottle of Plaquenil, the brand-name version of her prescription, which was priced at about \$2,000 and not covered by her insurance. With the help of a relative, Greenstein found a manufacturer's coupon that brought the price down to \$664.

She paid the price — 44 times her typical copay of \$15 — and expects the bottle will last her about a month.

"I could do that one time, but there will be people who will be bankrupted by this," she said. "They can't do it at all."



Sipa via AP Images

If she were to run out of her medication under normal circumstances, Greenstein said her quality of life would be severely affected, but she wouldn't worry for her health. But now, as someone with an autoimmune disease, she's also dealing with the fear that comes from being at higher risk for serious complications if she contracts COVID-19.

For the past week, she's had a cough and fatigue. At first, she chalked it up as symptoms of Sjögren's syndrome. When she got a fever Saturday, she contacted her doctor, who said she qualified to get tested for the coronavirus.

On Monday, she drove through a testing site and is waiting for results.

In the meantime, she's isolated herself in her home with her husband and two adult children. Her bedroom has become a makeshift quarantine while they wait for answers.

She's talked to her doctor about not being able to get her usual prescription, and her doctor told her other patients are having similar problems.

The drug has faced such an increase in demand that pharmacies in Mexico have reported Americans coming across the border for boxes of it, with some who "arrive with a slightly bossy attitude," the Dallas Morning News reported.

In the meantime, Greenstein said her doctor has suggested she could take one daily tablet, instead of the usual two, to stretch her supply.

She said she's tried that before, and her symptoms returned. For now, she hopes the supply will be replenished by the time she runs low in several weeks, but she doesn't know what she'll do after that.

Paying more than \$600 a month, she said, is not an option.

---

**From:** McWilliams, Carly  
**Sent:** Wednesday, March 25, 2020 11:46 AM  
**To:** Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>  
**Cc:** Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>  
**Subject:** REQUEST: Talkers on analysis and india lock down

Hi Mary Beth,

I am pulling info for the commissioners task force meeting. I know that cder is actively engaged on an analysis. Could you provide a few talking points to update the task force?

Could we get this by 2pm?

Thanks very much.

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 3/25/2020 7:54:15 PM  
**To:** Berrellez, Jessica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfaa6cc191f447659c6ab592b78f4af4-Jessica.Ber]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Fw: FDA 2019-nCoV SITREP - 25 March 2020  
**Attachments:** 46\_2019-nCoV Outbreak\_FDA SITREP\_25 March 2020.docx; 46\_2019-nCoV Outbreak\_FDA SITREP\_25 March 2020\_SUMMARY.docx

Hi Jess,

Awesome that this has been sent out.

It isn't clear which document is which - we need to make the names distinct tomorrow.

A

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 7:39 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>  
**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Measer, Gregory <Gregory.Measer@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>  
**Subject:** FDA 2019-nCoV SITREP - 25 March 2020

Hi,

Attached for your situational awareness is the 24 March FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Also attached is a beta-test of a 2-pg summary of the SITREP. Feedback on the summary SITREP would be appreciated.

Many thanks for your continued support. -Michael

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 3/30/2020 9:10:53 AM  
**To:** Sam Butler [sbutler@epic.com]  
**CC:** Phil Lindemann [Phil@epic.com]; Jackie Gerhart [jgerhart@epic.com]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Hunter, Nina L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8005f93bd66a4dfc83ebdaa67d9fd33b-NLH]; Corrigan-Curay, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]  
**Subject:** Re: Six boxes

This is really interesting.  
 In particular, it would be useful to see the changes in prescribing patterns over time (for example, is tocilizumab usage just starting to rise, or is the proportion of Rx flat). This will really help us understand how physicians are making decisions and when to look cross-sectionally at the system.  
 The COPD finding is indeed remarkable - not surprising, but still remarkable.

Adding my colleague Jacqueline Corrigan-Curay. (@Jacqueline - I can explain more about what this is when we talk today.)

---

**From:** Sam Butler <sbutler@epic.com>  
**Sent:** Monday, March 30, 2020 12:41 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Phil Lindemann <Phil@epic.com>; Jackie Gerhart <jgerhart@epic.com>  
**Subject:** RE: Six boxes

Amy

Here is some of what you asked for.  
 Notice the high percent of COPD in the ventilated patients

**(b)(5)**

Total Positive COVID patients

**(b)(4)**

Drug prescribed/ordered after pos test	Outpatient	Admitted	ICU	Ventilated	Male/Female	Deceased	Deceased	D/C
					%	Percent	Home	
Total	<b>(b)(4)</b>				55/45		3.5%	
Hydroxychloroquine					60/40	<b>(b)(4)</b>	6.5%	<b>(b)(4)</b>
Chloroquine								
Azithromycin				60/40		6.1%		



(Combination – Hydroxy/chloroquine + Azithromycin)

Tocilizumab

Sarilumab

Losartan

Eculizumab

Nitric oxide gas

Convalescent plasma (not sure how this would be coded)

(b)(4)

60/40

63/37

94/6

50/50

(b)(4)

5.9%

7.1%

6.3%

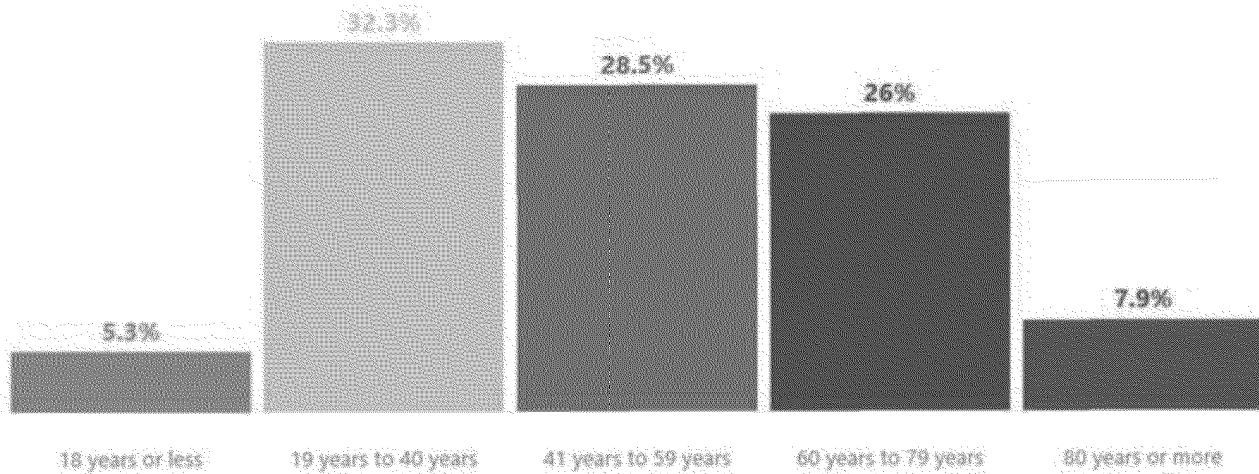
4.9%

(b)(4)

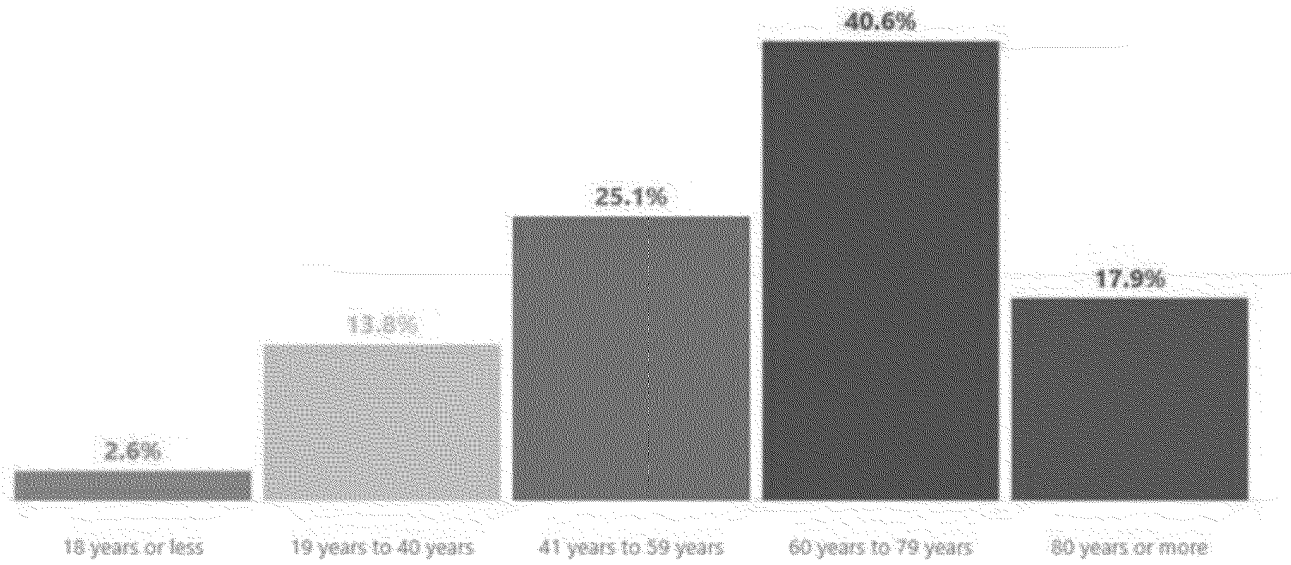
Hydroxychloroquine before positive test (b)(4)

Losartan Before positive test (b)(4)

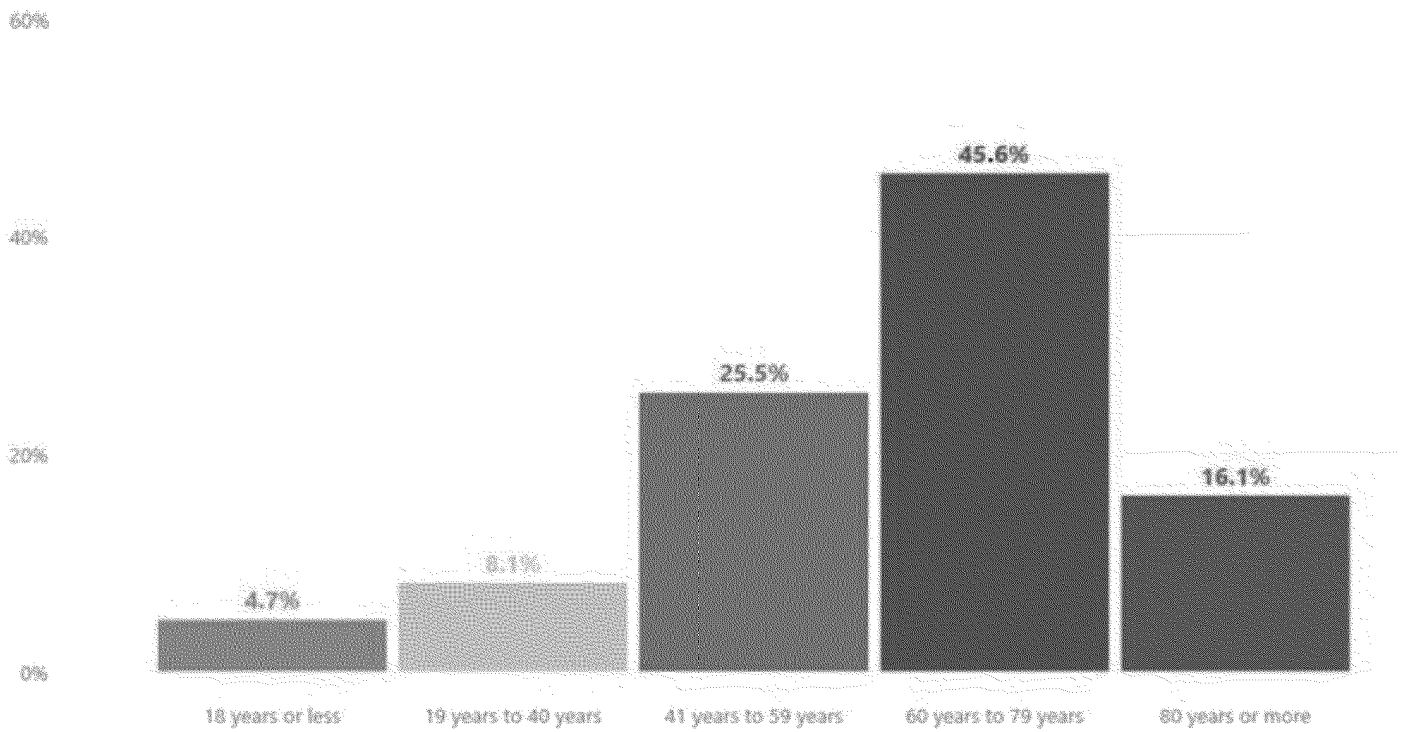
Positive COVID-19 age distribution



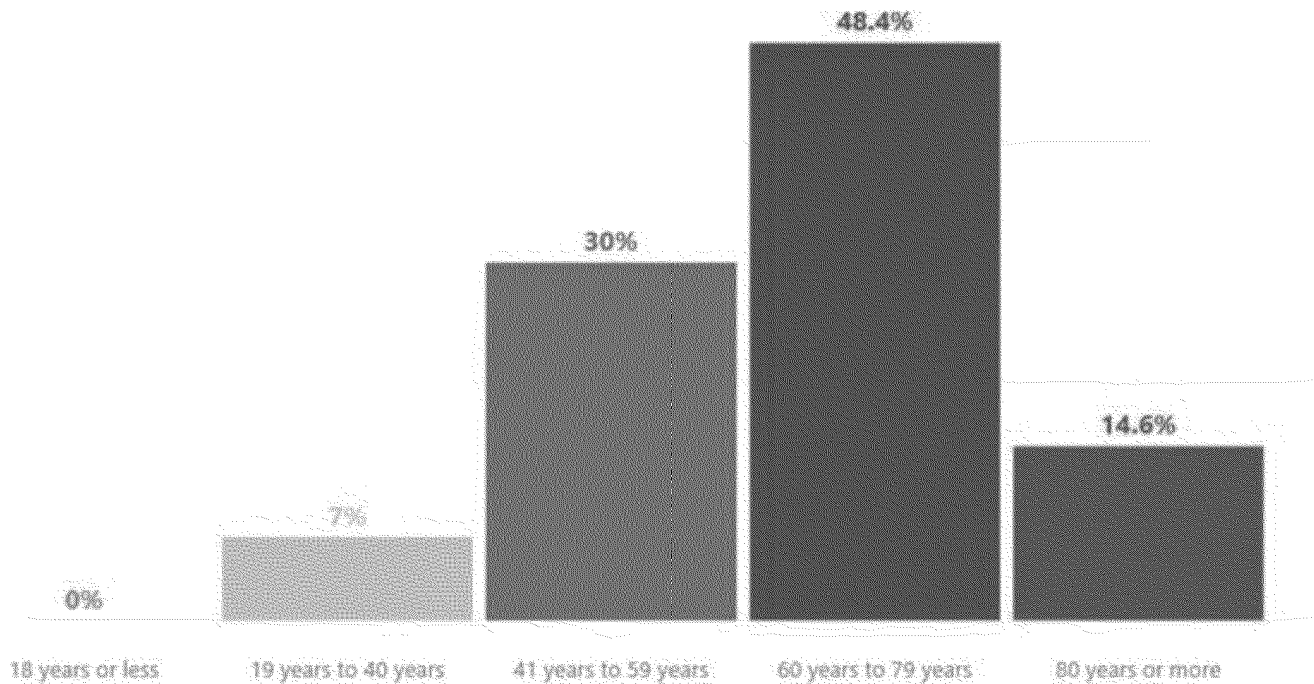
Admitted age distribution



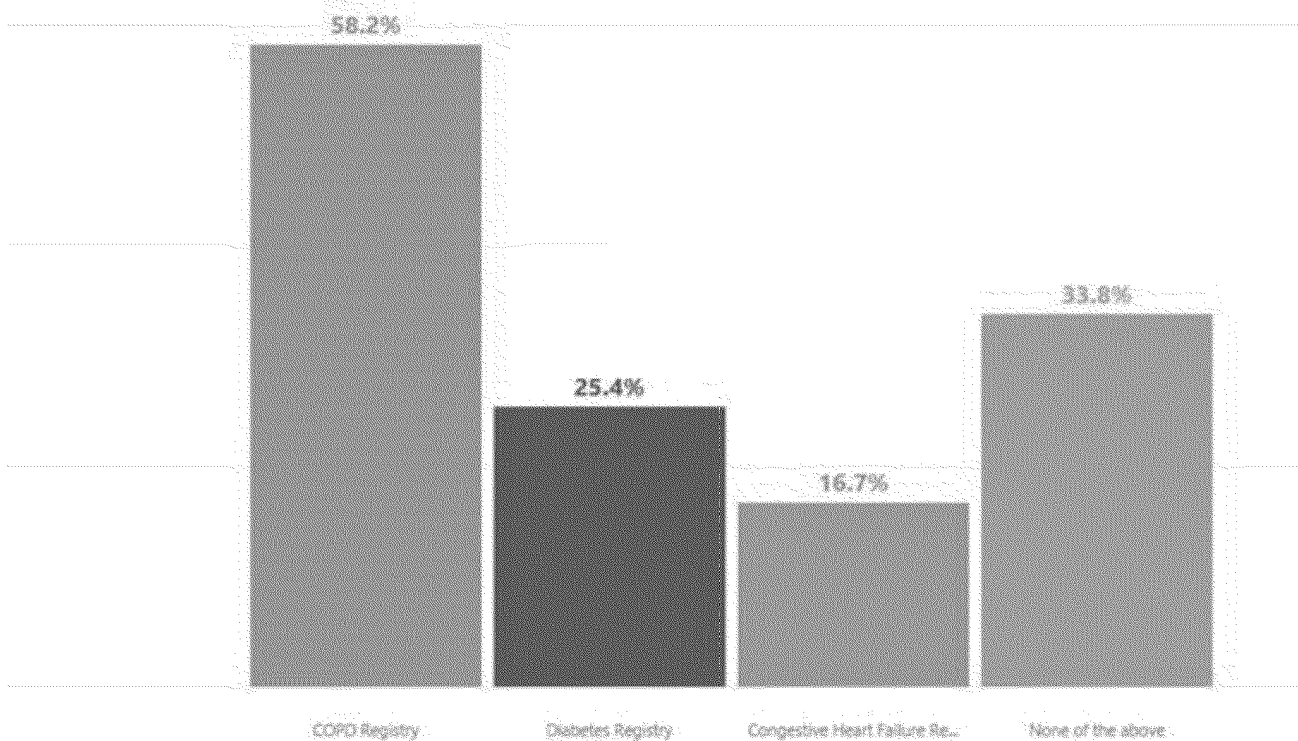
ICU age distribution



Ventilator age distribution



**Ventilator Comorbidity**



---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Sent:** Sunday, March 29, 2020 5:09 PM

**To:** Sam Butler <sbutler@epic.com>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Hunter, Nina L <Nina.Hunter@fda.hhs.gov>

**Subject:** Re: Six boxes

**External Mail.** Careful of links / attachments. Submit Helpdesk if unsure.

Sam -

I was typing too fast and realized that my list wasn't clear. Here is where I am ultimately going with this. I recognize that your current approach in Epic can only do so much - but the top line information that you can provide has great value too

Likelihood of RX of ...

- Hydroxychloroquine
- Chloroquine
- Azithromycin
- (Combination – Hydroxy/chloroquine + Azithromycin)
- Tocilizumab
- Sarilumab
- Losartan
- Eculizumab
- Nitric oxide gas
- Convalescent plasma (not sure how this would be coded)

Which COVID-19 patients are receiving these agents?

- Outpatient
- Inpatient-non-ICU
- Inpatient-ICU
- Ventilator?

Characterize by:

- Age
- Gender
- Resolution of disease (discharge from hospital to home without hospice [need to think about LTAC])
- Alive/dead

Predictors of likelihood to receive the agents?

● Outcomes:

- Death
- Time in hospital
- Time in ICU
- Transition to ICU
- \*\*\*Use categorical scale and outcome assessment timing from Cao et al NEJM 3/18/20
- Cross-sectional and time-to-event outcomes

Characteristics for propensity score matching that I have been considering:

- For ICU patients-

Ventilator  
Age  
FiO2  
Underlying pulmonary disease  
Other chronic underlying illness

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Sunday, March 29, 2020 6:00 PM  
**To:** Sam Butler <sbutler@epic.com>; Hunter, Nina L <Nina.Hunter@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>  
**Subject:** Re: Six boxes

Hi - I am looking forward to talking. Your information has really helped to shape my thinking today. I have been talking to various groups, and the different questions/topics/outcomes are outlined below. The drugs listed are those that we see in clinicaltrials.gov. We are sourcing information from other places as well that is coming in over the next 24 hours.

I want to make sure I am respectful of your time. Tomorrow we can walk through this list and what might be feasible and what isn't. Adding my colleagues Nina and Joe here.

Mimi can help us get a call on the calendar if that is easiest. Otherwise we can just text and find a time to talk.

Thank you!

Amy

Potentially being prescribed for COVID-19:  
Hydroxychloroquine  
Chloroquine  
Azithromycin  
(Combination – Hydroxy/chloroquine + Azithromycin)  
Tocilizumab  
Sarilumab  
Losartan  
Eculizumab  
Nitric oxide gas  
Convalescent plasma (not sure how this would be coded)

Who is receiving these agents Covid-19?

Outpatient  
Inpatient-non-ICU  
Inpatient-ICU  
Ventilator?

Age  
Gender  
Resolution of disease (discharge from hospital to home without hospice [need to think about LTAC])

Alive/dead

Outcomes:

Death

Time in hospital

Time in ICU

Transition to ICU

\*\*\*Use categorical scale and outcome assessment timing from Cao et al NEJM 3/18/20

Cross-sectional and time-to-event outcomes

Characteristics for propensity score matching:

For ICU patients-

Age

Ventilator

FiO2

Underlying pulmonary disease

Other chronic underlying illness

---

**From:** Sam Butler <sbutler@epic.com>

**Sent:** Sunday, March 29, 2020 4:20 PM

**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Subject:** Re: Six boxes

Sure give me more questions I can call you tomorrow

What time works for you

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Sent:** Sunday, March 29, 2020 2:56:35 PM

**To:** Sam Butler <sbutler@epic.com>

**Subject:** Re: Six boxes

**External Mail.** Careful of links / attachments. Submit Helpdesk if unsure.

I have been working on thinking through the questions all day. This is great.

Let me know if you want to talk again tonight or tomorrow is preferable.

---

**From:** Sam Butler <sbutler@epic.com>

**Sent:** Sunday, March 29, 2020 12:50 PM

**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

**Subject:** RE: Six boxes

**Covid positive patients** (b)(4) **total patients**

Tocilizumab (b)(4) not on

**Admitted COVID** (b)(4) **total patients**

Tocilizumab (b)(4) not on

**ICU patients** (b)(4) **total patients**

tocilizumab (b)(4)

**Ventilated (ever on a ventilator in the last 30 days) (b)(4) total patients**

Tocilizumab (b)(4)

Hydroxychloroquine (b)(4)

Added ventilator data for hydroxy and tocilizumab, this is ever on a ventilator and ever on the medications during this last 30 day

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Sunday, March 29, 2020 10:57 AM  
**To:** Sam Butler <sbutler@epic.com>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: Six boxes

**External Mail.** Careful of links / attachments. Submit Helpdesk if unsure.

Also, is there any chance you can generate a similar chart for tocilizumab?

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Sunday, March 29, 2020 11:50 AM  
**To:** Sam Butler <sbutler@epic.com>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: Six boxes

Hi - Thank you!

Quick questions -

1. Among people who are admitted vs ICU, is that cumulative or mutually exclusive? [See my little table pasted below - the numbers don't full add up, so I am trying to sort it out]
2. This is hydroxychloroquine only, right? Are you able to look at chloroquine too?

Thanks!

Amy

<b>RAW NUMBERS</b>				
	Never admitted to hospital	Admitted	Admitted and in ICU	TOTAL
On Hydroxycyl	<b>(b)(4)</b>			
Not on HCQ				
TOTAL				
<b>RAW NUMBERS</b>				
	Never admitted to hospital	Admitted but no ICU	Admitted and in ICU	TOTAL
On Hydroxycyl	<b>(b)(4)</b>			
Not on HCQ				
TOTAL				
<b>COLUMN PERCENT</b>				
	Never admitted to hospital	Admitted	Admitted and in ICU	
On Hydroxycyl	2%	70%	63%	
Not on HCQ	98%	30%	37%	
TOTAL				
<b>COLUMN PERCENT</b>				
	Never admitted to hospital	Admitted but no ICU	Admitted and in ICU	
On Hydroxycyl	2%	75%	63%	
Not on HCQ	98%	25%	37%	
TOTAL				
<b>ROW PERCENT</b>				
	Never admitted to hospital	Admitted	Admitted and in ICU	
On Hydroxycyl	4%	70%	26%	
Not on HCQ	78%	15%	8%	
TOTAL				
<b>ROW PERCENT</b>				
	Never admitted to hospital	Admitted but no ICU	Admitted and in ICU	
On Hydroxycyl	5%	59%	36%	
Not on HCQ	84%	8%	8%	

**From:** Sam Butler <[sbutler@epic.com](mailto:sbutler@epic.com)>  
**Sent:** Sunday, March 29, 2020 11:00 AM  
**To:** Abernethy, Amy <[Amy.Abernethy@fda.hhs.gov](mailto:Amy.Abernethy@fda.hhs.gov)>  
**Subject:** Six boxes

As of Midnight

All Patients with COVID-19 Positive **(b)(4)**

Patients never admitted **(b)(4)**

On Hydroxy **(b)(4)** Not on hydroxy **(b)(4)**



**Admitted Patients with COVID-19 positive (b)(4)**

On Hydroxy (b)(4) 70% Not on Hydroxy (b)(4) 30%

**ICU patients COVID-19 patients**

On Hydroxy (b)(4) 63% Not on hydrox (b)(4) 37%

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 3/30/2020 9:12:49 AM  
**To:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** see what you think...  
**Attachments:** DRAFT\_PR\_CTAP 03292020 1104am.docx

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: [amy.abernethy@fda.hhs.gov](mailto:amy.abernethy@fda.hhs.gov)

---

**From:** Pappas, Gregory [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=886E9F525F7242CE9B085DEEF5FFAEFE-GREGORY.PAP]  
**Sent:** 3/30/2020 12:43:00 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Waters, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bc2639c6ebd4ecc96e8c0fc6e7bb96f-Michael.Wat]; Hunter, Nina L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8005f93bd66a4dfc83ebdaa67d9fd33b-NLH]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Ross Martin [ross@360degreeinsights.com]; Ross Martin [ross@360degreeinsights.com]  
**Subject:** Re: surge plan for palliative care for University of Maryland Baltimore hospitals

I will ask Ross Martin at CRISP.

I doubt it as CRISP provides doctors with info about individual patients from other clinics. It's amazing how well it works. You click on the CRISP button which bring up a screen that show hospitalization, prescriptions, social services, and labs.

Again, Ross is one of the top docs who was a contender for ONC director.

Greg

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Date:** March 30, 2020 at 11:33:10 AM EDT  
**To:** Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>  
**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>, Hunter, Nina L <Nina.Hunter@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: surge plan for palliative care for University of Maryland Baltimore hospitals

Thank you!

I have been wondering if there is a way to work with HIEs to understand shortages. Any thoughts there? Also, could be another avenue to get data on patterns of care.

---

**From:** Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 9:31 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Waters, Michael <Michael.Waters@fda.hhs.gov>  
**Subject:** FW: surge plan for palliative care for University of Maryland Baltimore hospitals

Hi Amy,

You are probably way to busy for this, but this weekend Carla and I finalized a proposal to ramp up PC services using trained volunteers.

Carla is working with leadership at the two UoM hospitals in Baltimore to implement the plan

I have two RWE proposals that have relevance to the pandemic. One is to deal with shortages but that is a post emergency plan for the future. (that is the GSRS, Global Substance Registration System). Expect that White Paper end of

this week. It will be something to tuck away for after action. I have also been working with CRISP, the four state Health Information Exchange (Maryland, Pennsylvania, Delaware, and West Virginia). They are already highly functional. You may know Ross Martin who is a consultant to CRISP. They are working with FDA/SHIELD to push out uniform and harmonized coding to capture data on COVID-19 (solve interoperability problems). This will then be available in clinical EHR systems and shared across all clinics/hospital. They are preparing a proposal that I will send to you.

I've cc'ed Mike Waters CDRH who leads SHIELD on this email.

Greg

---

**From:** Hunter, Nina L [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8005F93BD66A4DFC83EBDAA67D9FD33B-NLH]  
**Sent:** 3/30/2020 5:45:41 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Common Data Elements - proposed list  
**Attachments:** data elements 033020v4.docx; Copy of Copy of Data elements\_COVID-19\_V3.xlsx

Please see attached proposed common data elements (named v.4). It's not a perfect match to the Excel Spreadsheet (v.3). They still need to be aligned – work in progress.

Current sources include (Word is all inclusive):

RWE-T and Vanderbilt

The Common Data Model Harmonization project that is currently running at NIH/NCATS

NIH/FDA Interagency Clinical Outcomes Assessment Working Group

PCORI and PCORNET (\*I went through all the slides I had)

FDA internal consult with CDER/OND

Our review of three recent publications on the New England Journal of Medicine: i.e., Cao et al. (a trial on lopinavir-ritonavir), Holshue et al. (a case report on remdesivir), and Duan et al. (a trial on convalescent plasma therapy)

Information on the design of WHO's SOLIDARITY trial

Thanks,  
Nina

---

**From:** Hoffman, Allison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEED30BE6A004DD29AC6C7F8EBCADBC5-ALLISON.HOF]  
**Sent:** 3/31/2020 7:44:56 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]  
**Subject:** Meeting prep for Health Evolution Summit Apr 1-2 2020  
**Attachments:** Meeting prep sheet Health Evolution Summit Apr 1 2020.docx

Hi Amy,

Please see the attached meeting prep for tomorrow and Thursday's panels with Health Evolution. Both panels will include COVID19 questions (highlighted) so please refer to the latest reactive talking points from Andy Tantillo.

Allison

---

**From:** Amjad Riar; (b)(6)  
**Sent:** 3/31/2020 7:04:18 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: Greetings - urgent

Thank you! Any.  
Will update you how things go.  
Amjad  
Amjad Riar, MD FACP FAAHPM FAAPL HMDC CPE

On Mar 31, 2020, at 4:00 PM, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov> wrote:

Hi Amjad,  
Thank you for your message.  
I am cc'ing Anand Shah from FDA here; his team can help to answer your question.  
Take care,  
Amy

---

**From:** Amjad Riar; (b)(6)  
**Sent:** Tuesday, March 31, 2020 12:55 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; (b)(6)  
**Subject:** Re: Greetings - urgent

Hi Amy,  
I trust you are doing well. As our country deals with with COVID-19 crisis. Current modeling suggest we can see up-to 2000 deaths/day. This challenge is not only due to limited access to testing but further compounded by lack of PPE supplies.

I am so desperately trying to help small to medium size health care organizations to be able to purchase PPE from my brothers well established suppliers and manufacturers overseas. He has a overseas medical supplies company for last fifteen years and have strong relationships with these manufacturers. I have collected Supplies requests from Several organizations and he was able to collect the actual supplies but We do not have way to get the supplies here to US.

I am reaching out to see if you know or point my to someone at FDA who can guide me to get these PPE for several organizations in need here at home.  
My interest in this process is to only step in and help protect our fellow doctors and nurses on frontlines.

Please let me know there is anything at all you can do from your standpoint.  
I am looking forward to hearing from you. You can also call me at my Cell number is (240) 388-1414  
Please be safe!  
Fondly,  
Amjad

Amjad Riar, MD FACP FAAHPM FAAPL HMDC CPE  
Listen to MyNHPCO Podcasts (#14,#15,#16) at:  
<https://podcasts.apple.com/us/podcast/hpm-talk/id1386378928>

American association of physician leadership: <http://info.physicianleaders.org/cpe20>  
<https://youtu.be/o2-Im6gY1a>

On Feb 4, 2019, at 6:29 AM, Amy Abernethy, M.D. <[amy.abernethy@duke.edu](mailto:amy.abernethy@duke.edu)> wrote:

Hi Amjad - I apologize for the belated email; it has been a whirlwind 2 months.

Thanks for the warm message. I am excited and honored to be able to join FDA.

Thank you for all that you do. It is important for all of us to keep pushing palliative care forward.

Take care,

Amy

---

**From:** Amjad Riar; (b)(6)  
**Sent:** Wednesday, December 19, 2018 9:13 PM  
**To:** Amy Abernethy, M.D.  
**Subject:** Re: Greetings

Greetings Amy,  
It's been a while since we last spoke. I trust this note finds you doing well.

Two things:

1) Congratulations!!! For FDA position. well deserved. Who can better represent the patients and our speciality. It is a privilege to know you and crossing path with you :)

2) I wish you a very happy holiday season, Merry Christmas and Happy New Year!

If you are planning to be at next AAHPM meeting in FL, I would love to catching up there or in whenever you are in DC or Rockville.

Best regards,  
Amjad

Amjad Riar, MD FAAHPM HMDC CPE  
National Medical Director | Post-Acute Care  
Optum

Amjad Riar, MD FAAHPM HMDC CPE



On Jun 7, 2014, at 8:38 AM, Amy Abernethy, M.D. (b)(6) wrote:

Hi Amjad,

What a wonderful note. Thank you so much!

The Palliative Care Research Cooperative Group is starting to get traction, and practical study results are starting to come out. Wahoo! Rocking and rolling along.

I look forward to seeing you again at many Academy and other events.

Please take care,

Amy

---

**From:** Amjad Riar (b)(6)

**Date:** Friday, June 6, 2014 at 8:24 PM

**To:** Amy Abernethy (b)(6)

**Subject:** Greetings

Hi Amy:

Hope you are enjoying the summer. I like to reach out to you and thank you for your work on recent study "Discontinuation of statin use near end of life improved QOL" Your work will us educating our cardiology folks and patient families. Sorry I missed your recent talk in Richmond VA. I had all the plans to attend but schedule conflicts did not allow. Looking forward to see you in Philly or Ascend program.

Best Regards,  
Amjad

--  
*Amjad Riar, MD FAAHPM  
Palliative Medicine Physician  
Vice Chairman Inova Loudoun Hospital Department of Medicine  
Vice Chairman Maryland Governor's Commission on South Asian Affairs*

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 4/2/2020 10:50:46 AM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]  
**Subject:** Re: Greetings - urgent

Totally agree

Thanks for all that you are doing, Brooke.

Take care

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Thursday, April 2, 2020 10:31 AM  
**To:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** RE: Greetings - urgent

Hi Brooke -  
You did great – and thanks for your efforts over the past many weeks  
Best,  
Anand

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Sent:** Thursday, April 2, 2020 10:23 AM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** RE: Greetings - urgent

Hi Amy and Anand,

My apologies if my second message sounded too firm, but I've been very uncomfortable fielding the many requests for "urgent" personal assistance through personal contacts of those wanting to sell medical products to private sources for the response (e.g., from the WH, etc.). The approach I've taken for these is to route them through appropriate channels, which includes providing links to publicly-available information.

Thanks!  
Brooke

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Thursday, April 02, 2020 10:17 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Subject:** FW: Greetings - urgent

Amy – closing the loop here - FYSA – He should have everything he needs from Brooke.  
Anand

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Sent:** Thursday, April 2, 2020 10:02 AM

To: Amjad Riar (b)(6)  
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>  
Subject: RE: Greetings - urgent

Amjad,

Anand and I discussed this and the following might be helpful, in addition to the information we shared in my initial email. We can only share publicly available sources of information and encourage you to please consult the links we've provided you. As noted in one the public links below:

- **If my respirators are authorized for use under the EUA, what do I need to do to import them? Who do I contact if my authorized respirator has import issues?** Import information can be found on the Custom and Border Patrol website, CSMS Message #42124872 External Link Disclaimer. Please contact COVID19FDAIMPORTINQUIRIES@fda.hhs.gov or 301-796-0356 to resolve entry issues for shipments.

If you are interested in selling or donating product to support the USG response, please visit FEMA's How to Help page, which includes detailed information about submitting information on medical product requests:

- <https://www.fema.gov/coronavirus/how-to-help>

I cannot provide you with any additional information.

Kind regards,  
Brooke

---

From: Amjad Riar (b)(6)  
Sent: Thursday, April 02, 2020 12:58 AM  
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>  
Subject: Re: Greetings - urgent

Hello Brooke,  
Thank you for sharing the links to resources.

I guess the ask would be if I am not a company but have connections in China for bringing these PPE for several organizations who reachEd out to me. How can I help them and my fellow frontline providers?  
I reached out to Dr Abernathy to get FDA to help me out in this emergency public health crisis situation. It might not be a usual course for your office but you will agree these are not very usual times either.

Are you able to help? I hope you can.  
Thanks,  
Dr. Riar

Amjad Riar, MD FACP FAAHPM FAAPL HMDC CPE

On Apr 1, 2020, at 9:38 AM, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov> wrote:

Dear Amjad,

Based on below, it's not quite clear to what type of PPE this inquiry is referring. As a first step, it would be helpful to review FDA's Emergency Use Authorization (EUA) page for the PPE EUAs that have been issued for COVID-19.

- <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe>
- One of the EUAs is specifically focused on "Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators."
  - See *Non-NIOSH Approved Respirator EUA FAQ* webpage for information about how to import respirators authorized for use under the EUA: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/non-niosh-approved-respirator-eua-faq>

Helpful information about gloves for COVID can be found here:

- <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/fags-shortages-medical-gloves>
- This page includes information about *How can manufacturers of medical gloves who may be considering increasing availability of these products to the U.S. market engage with the FDA?* and *Which medical gloves are FDA-cleared?*

If you are interested in selling or donating product to support the USG response, please visit FEMA's How to Help page, which includes detailed information about submitting information on medical product requests:

- <https://www.fema.gov/coronavirus/how-to-help>

Thanks,  
Brooke

---

**From:** Amjad Riar [redacted] (b)(6)  
**Sent:** Tuesday, March 31, 2020 7:03 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Subject:** Re: Greetings - urgent

Dear Anand and Brooke,

Thank you for a prompt reply response and please to meet you.

Please let me know how your team can help us with this?  
I am looking forward to speaking and working with your team.  
Best,  
Amjad

Amjad Riar, MD FACP FAAHPM FAAPL HMDC CPE

On Mar 31, 2020, at 4:03 PM, Shah, Anand <Anand.Shah@fda.hhs.gov> wrote:

Hi Brooke –  
Can you please connect with Amjad on the request below?

Thanks,  
Anand

---

**From:** Shah, Anand  
**Sent:** Tuesday, March 31, 2020 4:02 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Amjad Riar <(b)(6)> Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** RE: Greetings - urgent

Thanks, Amy, for the intro to Amjad. I'll follow up in a separate note to follow  
Anand

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 4:00 PM  
**To:** Amjad Riar <(b)(6)>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Re: Greetings - urgent

Hi Amjad,  
Thank you for your message.  
I am cc'ing Anand Shah from FDA here; his team can help to answer your question.  
Take care,  
Amy

---

**From:** Amjad Riar <(b)(6)>  
**Sent:** Tuesday, March 31, 2020 12:55 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov> <(b)(6)>  
**Subject:** Re: Greetings - urgent

Hi Amy,  
I trust you are doing well. As our country deals with with COVID-19 crisis. Current modeling suggest we can see up-to 2000 deaths/day. This challenge is not only due to limited access to testing but further compounded by lack of PPE supplies.

I am so desperately trying to help small to medium size health care organizations to be able to purchase PPE from my brothers well established suppliers and manufacturers overseas. He has a overseas medical supplies company for last fifteen years and have strong relationships with these manufacturers. I have collected Supplies requests from Several organizations and he was able to collect the actual supplies but We do not have way to get the supplies here to US.

I am reaching out to see if you know or point my to someone at FDA who can guide me to get these PPE for several organizations in need here at home.  
My interest in this process is to only step in and help protect our fellow doctors and nurses on frontlines.

Please let me know there is anything at all you can do from your standpoint.

I am looking forward to hearing from you. You can also call me at my Cell number is <(b)(6)>

Please be safe!

Fondly,

Amjad

Amjad Riar, MD FACP FAAHPM FAAPL HMDC CPE

Listen to MyNHPCO Podcasts (#14,#15,#16) at:

<https://podcasts.apple.com/us/podcast/hgm-talk/id1386378928>

American association of physician leadership: <http://info.physicianleaders.org/cpe20>  
<https://youtu.be/o2-lm6gYla>

On Feb 4, 2019, at 6:29 AM, Amy Abernethy, M.D. [REDACTED] wrote:

Hi Amjad - I apologize for the belated email; it has been a whirlwind 2 months.

Thanks for the warm message. I am excited and honored to be able to join FDA.

Thank you for all that you do. It is important for all of us to keep pushing palliative care forward.

Take care,

Amy

---

**From:** Amjad Riar [REDACTED]  
**Sent:** Wednesday, December 19, 2018 9:13 PM  
**To:** Amy Abernethy, M.D.  
**Subject:** Re: Greetings

Greetings Amy,  
It's been a while since we last spoke. I trust this note finds you doing well.

Two things:

1) Congratulations!!! For FDA position. well deserved. Who can better represent the patients and our speciality. It is a privilege to know you and crossing path with you :)

2) I wish you a very happy holiday season, Merry Christmas and Happy New Year!

If you are planning to be at next AAHPM meeting in FL, I would love to catching up there or in whenever you are in DC or Rockville.

Best regards,  
Amjad

Amjad Riar, MD FAAHPM HMDC CPE  
National Medical Director | Post-Acute Care  
Optum

Amjad Riar, MD FAAHPM HMDC CPE  
On Jun 7, 2014, at 8:38 AM, Amy Abernethy, M.D. [REDACTED] wrote:

Hi Amjad,

What a wonderful note. Thank you so much!

The Palliative Care Research Cooperative Group is starting to get traction, and practical study results are starting to come out. Wahoo! Rocking and rolling along.

I look forward to seeing you again at many Academy and other events.

Please take care,

Amy

---

**From:** Amjad Riar; (b)(6)  
**Date:** Friday, June 6, 2014 at 8:24 PM  
**To:** Amy Abernethy; (b)(6)  
**Subject:** Greetings

Hi Amy:

Hope you are enjoying the summer. I like to reach out to you and thank you for your work on recent study "Discontinuation of statin use near end of life improved QOL" Your work will us educating our cardiology folks and patient families. Sorry I missed your recent talk in Richmond VA. I had all the plans to attend but schedule conflicts did not allow. Looking forward to see you in Philly or Ascend program.

Best Regards,  
Amjad

--

*Amjad Riar, MD FAAHPM  
Palliative Medicine Physician  
Vice Chairman Inova Loudoun Hospital Department of Medicine  
Vice Chairman Maryland Governor's Commission on South Asian Affairs*

---

**From:** McLatchy, Johanna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=895AD3BDE51342D5817826CCC9BC1BA7-MCLATCHYJ]  
**Sent:** 4/3/2020 7:59:52 AM  
**To:** McLatchy, Johanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=895ad3bde51342d5817826ccc9bc1ba7-MCLATCHYJ]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Buhse, Lucinda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03c54017a02447e1aea701cbe7c11aab-BUHSEL]; Schick, Andreas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce65e11cf29b486b99da49528c348cd8-Andreas.Sch]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Bina, Christine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a515888c96f84c88956d6c29071abe0d-BINAC]; Rosenberg, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27759625f414830a7d9510eef02fc74-ROSENBERGMA]; Hornung, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab78f29c3a884a86bd5ba9e45124d704-Matthew.Hor]; Burrow, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ef64288121042d68d325481c83787df-DCB]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]; Budashewitz, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38f690da6364b3283d1940fb216e3ee-Philip.Buda]; Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]; Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fef403a-CLARKEM]; Ngan, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7a30838c8bc49428cbb4959ae8ed6c-NGANK]; INC\_2020-01\_2019-nCoV@sharepoint.fda.gov; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Tuckett, Gayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9be0cae2f3747c7a016fca25074c0bb-Gayle.Tucke]; Buckman-Garner, ShaAvhrée [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a52027392a4357aa07e5c8eaed1eeb-BUCKMANS]; Sherwood, Edward M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=951b510e828a4182ace7e2a805e42f50-SHERWOODT]; Sharma, Khushboo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0c8e73a04e14d15bb313bf0bc66ded6-SHARMAKH]; Stein, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d30a87acb0184261961264ba984b0a51-Peter.Stein]; Zadecky, Leo



[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Choe, Sally  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03634cd6d8434c968f86bafa4f15f9f6-Sally.Choel]; Bernstein, Jessica  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acb893b722614d84b1042b58f413b875-Jessica.Ber]; Stone, Eric  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Van Pool, Kendall  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Corrigan-Curay, Jacqueline  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]; Jungman, Elizabeth  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Sipes, Grail  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Slack, Mary Ann  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1652127b1024caaa9ccd95114ece253-SLACKM]; Bugin, Kevin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]; Flanagan, Keith  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15dcaab5c1ea4007adbc43e9acd413a6-Keith.Flana]; Mullin, Theresa  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=816f51c336a9449db257955b88720bdd-TMullin]; Saliba, Jouhayna  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e355d8ca118640c09f8f584501bf5b44-SALIBAJ]; Thakur, Emily  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb8cb71ad87e49999ae9d28fe0b81452-THAKURE]; Dal Pan, Gerald  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=273ac18eca2349d6996990ea22ab1a5b-DALPANG]; Abernethy, Amy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Defina, Matt  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a17f2a69b7674aeb894c23c15b2f5c1f-Matt.Defina]

CC: Kopcha, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e25d758ee8ba4b69987fd443214fd926-Michael.Kop]; Hunt, Michie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7815b5291a944498653374dada35d91-HUNTM]; Ruiz-Barnes, Cesar \*  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e35c56f8c0f4709a59313783fef2513-Cesar.Ruiz-]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]

**Subject:** COVID-19: CDER Senior Leadership Meeting - Call In: 877-939-2720; PC (b)(6) Agenda Added

**Attachments:** CDER COVID-19 Leadership Mtg Agenda APR 03 2020docx.docx

**Location:** Bldg 51/ Room 1219

**Start:** 4/3/2020 11:00:00 AM

**End:** 4/3/2020 12:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Woodcock, Janet; Cavazzoni, Patrizia; Throckmorton, Douglas C; Jensen, Valerie E; Buhse, Lucinda; Schick, Andreas; Roberts, Rosemary; Leissa, Brad G; Farley, John; Patel, Paras M; Bina, Christine; Rosenberg, Matthew; Hornung, Matthew; Burrow, David; Shreeve, Chris; Budashewitz, Philip; Rawlings, Kimberly; Ashley, Donald; Mary Clarke; Ngan, Kelly (Kelly.Ngan@fda.hhs.gov); INC\_2020-01\_2019-nCoV@sharepoint.fda.gov; Birnkrant, Debra B; Tuckett, Gayle; Buckman-Garner, ShaAvhrée; Sherwood, Edward M; Sharma, Khushboo; Stein, Peter; Zadecky, Leo; Choe,

---

Sally; Bernstein, Jessica; Stone, Eric; Van Pool, Kendall; Corrigan-Curay, Jacqueline; Jungman, Elizabeth; Sipes, Grail; Slack, Mary Ann; Bugin, Kevin; Flanagan, Keith; Mullin, Theresa; Saliba, Jouhayna; Thakur, Emily; Dal Pan, Gerald; Abernethy, Amy; Defina, Matt

*Agenda to be shared in advance of the meeting.*

Call In Information: 877-939-2720; Participant Code: (b)(6)

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): (b)(6)

Meeting password: (b)(6)

Join meeting

**Join by phone**

Tap to call in from a mobile device (attendees only)

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to <http://help.webex.com>

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 4/3/2020 12:21:35 PM  
**To:** jose.baselga@astrazeneca.com  
**CC:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Fw: URGENT - Astrazeneca proposal for COVID treatment protocol  
**Attachments:** BTK and COVID19\_MASTER\_updated.docx

Dear Jose,

It is good to hear from you. Thank you.

I am cc'ing Anand Shah here; he and his team is helping to make sure that we are getting concepts and requests the right attention.

Please take care,

Amy

---

**From:** Baselga, Jose <Jose.Baselga@astrazeneca.com>  
**Sent:** Friday, April 3, 2020 12:16 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** URGENT - Astrazeneca proposal for COVID treatment protocol

Dear Amy,

It has been a while, I hope you are well and thank you so much for your leadership in these challenging time.

I am contacting to seek your advice and guidance on how to move forward quickly on a very exciting clinical trial with Acalabrutinib to decrease COVID 19 related assisted ventilation and mortality.

Lou Staudt and Wyndham Wilson at the NIH/Walter Reed have been working on the hypothesis that Btk inhibition effectively targets the inflammatory response associated with moderate to severe COVID-19 infections and reduce the need for mechanical ventilation and death. The preclinical data is compelling. In addition, they have treated a few patients at the NIH that were about to be intubated and they recovered very quickly. I have personally been talking to them and I am convinced that there is a powerful effect.

We have submitted the proposal to CTAP and would like to start as soon as possible.

Thank you.

All the best,

Jose

**Jose Baselga, MD, PhD.**  
EVP & President Oncology R&D  
AstraZeneca, One MedImmune way  
Gaithersburg, MD 20858, US  
jose.baselga@astrazeneca.com

Executive Assistant:  
Elizabeth Asafu-Adjaye  
elizabeth.asafu-adjaye@astrazeneca.com

---

**Confidentiality Notice:** This message is private and may contain confidential and proprietary information. If you have received this message in error, please notify us and remove it from your system and note that you must not copy, distribute or take any action in reliance on it. Any unauthorized use or disclosure of the contents of this message is not permitted and may be unlawful.

---

**From:** Mark (b)(6)  
**Sent:** 4/9/2020 8:14:46 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** The Covid -19 Drug Leronlimab

CytoDyn has a drug Leronlimab that has positive results on people in the treatment of Covid-19 patients. The UK has requested it. Why can't this drug be approved expeditiously?

Hydroxychloroquine has cardiac complications and that may rule me and many others out from taking it.

Thank you for all you do.

Time is of essence.

Mark Terry

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 4/14/2020 3:34:20 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: ReaganUdall press release (for awareness)  
**Attachments:** COVID Treatment Hub Press Release 04 11 2020SCW.docx

Sharing with you for awareness. RUF is issuing news release on this tomorrow morning.

---

**From:** Rebello, Heidi  
**Sent:** Monday, April 13, 2020 9:21 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** FW: ReaganUdall press release (for awareness)

Susan Winckler, former CoS when Dr. vE was Commissioner, has joined ReaganUdall Foundation as CEO (May 1, she is serving as Senior Advisor for now).

She is sharing the latest news release of the Foundation's COVID-19 patient resource re: clinical trials/expanded access/etc. That draft is attached; let me know if you have any concerns. It's slated for Tuesday.

---

**From:** Susan Winckler <[swinckler@reaganudall.org](mailto:swinckler@reaganudall.org)>  
**Sent:** Saturday, April 11, 2020 2:25 PM  
**To:** Rebello, Heidi <[Heidi.Rebello@fda.hhs.gov](mailto:Heidi.Rebello@fda.hhs.gov)>  
**Subject:** ReaganUdall press release (for awareness)

Heidi:

First, sorry for dropping a note in your inbox when I am sure it is (literally and figuratively) over-flowing.

Second, I'll admit that I am SO excited to be moving back into the 'help the FDA' world by working at the ReaganUdall Foundation. Until I start as CEO on May 1, I'm serving as a senior advisor now to get some things moving.

Third, it is in that role that I'm reaching out now. I understand there were some machinations related to the announcement of the Foundation's COVID-19 patient resource re: clinical trials/expanded access/etc., so I wanted to make sure you were in the loop on the current version of our release. That draft is attached for your awareness; I think our characterization of the FDA role is accurate. But let me know if this gives you heart burn. We probably won't issue until Tuesday, so no rush.

Fourth, give me a shout if I can EVER be helpful. Hope you're getting a chance to enjoy at least a bit of the weekend.

Susan

(cell is (b)(6))

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 4/27/2020 9:10:22 AM  
**To:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Fw: PDC CMAG Planning  
**Attachments:** OND COVID All Hands 20200421 final.pptx

Useful to review.  
Need to know accrual information for the clinical trials

---

**From:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>  
**Sent:** Monday, April 27, 2020 8:58 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Hunter, Nina L <Nina.Hunter@fda.hhs.gov>  
**Subject:** RE: PDC CMAG Planning

FYI – OND Town Hall slides from last week if interested. OND COVID All Hands 20200421 final.pptx

Kind Regards,  
April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



-----Original Appointment-----

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Friday, April 10, 2020 8:54 AM  
**To:** Abernethy, Amy; Franklin, Joseph; Valo, Gina; Hoffman, Allison; Nguyen, Mimi; Alexandrow, April; Hunter, Nina L  
**Subject:** PDC CMAG Planning  
**When:** Monday, April 27, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** WebEx

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code) (b)(6)

(b)(6)

Meeting password: (b)(6)

Join meeting

**Join by phone**

Tap to call in from a mobile device (attendees only)

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

If you are a host, [go here](#) to view host information.

Need help? Go to <http://help.webex.com>

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 4/29/2020 5:51:30 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Fw: Two more findings  
**Attachments:** COVID-19 Population Characteristics Sex and Age Group - 2020-04-21 (reformat in progress).docx; Ibuprofen and COVID-19 Severity 22-Apr-2020.docx

---

**From:** Sam Butler <sbutler@epic.com>  
**Sent:** Thursday, April 23, 2020 10:26 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Two more findings

Two more



---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 5/1/2020 1:16:36 PM  
**To:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]  
**Subject:** Fw: Two more findings  
**Attachments:** COVID-19 Population Characteristics Sex and Age Group - 2020-04-21 (reformat in progress).docx; Ibuprofen and COVID-19 Severity 22-Apr-2020.docx

---

**From:** Sam Butler <sbutler@epic.com>  
**Sent:** Thursday, April 23, 2020 10:26 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** Two more findings

Two more

---

**From:** Alexandrow, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AE28FB4C1E044E2E9BD727F7F6A3EBB3-ALEXANDROWA]  
**Sent:** 5/5/2020 8:48:24 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: COVID-19 Clinical Data Analysis  
**Attachments:** 2020-04-24\_COVID\_Update.pdf; 2020-04-25\_COVID\_Update.pdf; 2020-04-28\_COVID\_Update.pdf; 2020-04-03\_COVID\_UPDATE.pdf; 2020-04-01\_COVID\_UPDATE.pdf; 2020-04-07\_COVID\_UPDATE.pdf; 2020-04-10\_COVID\_Update.pdf; 2020-04-10\_COVID\_Update\_ed2.pdf; 2020-04-14\_COVID\_Update.pdf; 2020-04-17\_COVID\_Update.pdf; 2020-04-21\_COVID\_Update.pdf; 2020-04-23\_COVID\_Update.pdf

FYI from the CDC Library

Kind Regards,

April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



---

**From:** Knuth, Martha (CDC/DDPHSS/OS/OLS) <mto4@cdc.gov>  
**Sent:** Monday, May 4, 2020 12:08 PM  
**To:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>; Honeycutt, Sally (CDC) <ejk6@cdc.gov>  
**Subject:** RE: COVID-19 Clinical Data Analysis

Hi April,

I would be happy to! Attached are all of our Science Updates. They are coming out of the daily search that I do and then a whole expert team reviews studies and summarizes them.

Only caveat we have is please don't share outside of FDA. We are summarizing and include tables from the studies which all of CDC has access to but other outside organizations might not.

I hope they help! I can keep sending them along if you like them.

All the best,  
Martha Knuth, MLIS  
Librarian

**Stephen B. Thacker CDC Library**  
Office of Library Science  
Office of Science  
Centers for Disease Control and Prevention  
Roybal Campus/Global Communications Center/ Bldg 19  
1600 Clifton Road, N. E., MS H19-1  
Atlanta, GA 30329  
**Office:** 404.718.5375  
**Email:** mt4@cdc.gov



CDC Office of Science  
QUALITY | INTEGRITY | INNOVATION

---

**From:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 11:31 AM  
**To:** Knuth, Martha (CDC/DDPHSS/OS/OLS) <mto4@cdc.gov>; Honeycutt, Sally (CDC/DDPHSS/CSELS/DSEPD)

<ejk6@cdc.gov>

**Subject:** RE: COVID-19 Clinical Data Analysis

Martha,

Thank you so much for sharing, I really appreciate it and look forward to the update. If there are any other special edition topic systematic review papers, please let me know.

Kind Regards,

April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



---

**From:** Knuth, Martha (CDC/DDPHSS/OS/OLS) <mt4@cdc.gov>  
**Sent:** Monday, May 4, 2020 8:05 AM  
**To:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>; Honeycutt, Sally (CDC) <ejk6@cdc.gov>  
**Subject:** RE: COVID-19 Clinical Data Analysis

Hi April,

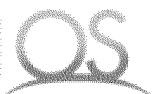
For some additional follow-up, our EOC team that does our COVID-19 research summaries said it was ok to share their special edition that was done on hydroxychloroquine with our partners at FDA back on April 3rd. They are also planning on doing an update soon which I'll pass your way!

Just a note, these summaries are not for public distribution so we'd appreciate it if you kept it internal.

Disclaimer: "Any third party published materials including but not limited to articles, abstracts, charts, or data included in this COVID-19 Science Update Digest are provided for internal agency or U.S. Government educational purposes only. Some resources provided herein may be restricted in their use outside the agency or U.S. Government. Any other uses of such material including incorporating data into publications, guidance, or presentations, will require an examination of potential copyright or other intellectual property implications, as well as appropriate attribution."

All the best,  
Martha Knuth, MLIS  
Librarian

**Stephen B. Thacker CDC Library**  
Office of Library Science  
Office of Science  
Centers for Disease Control and Prevention  
Roybal Campus/Global Communications Center/ Bldg 19  
1600 Clifton Road, N. E., MS H19-1  
Atlanta, GA 30329  
**Office:** 404.718.5375  
**Email:** mt4@cdc.gov



CDC Office of Science  
QUALITY | INTEGRITY | INNOVATION

---

**From:** Knuth, Martha (CDC/DDPHSS/OS/OLS)

**Sent:** Friday, May 1, 2020 4:16 PM

**To:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>; Honeycutt, Sally (CDC/DDPHSS/CSELS/DSEPD) <ejk6@cdc.gov>

**Subject:** RE: COVID-19 Clinical Data Analysis

Hi April,

I am so happy that the database has been helpful! Let me know if your team would like an EndNote file of the full database. You can pull all articles in the database that are on hydroxychloroquine. (Let me know if you need assistance to do this). That's a little easier to search sometimes and I'd be happy to email it to you regularly. Let me know what would help you and your team the most!

I contacted our Emergency Operations Center team who are working on some of this research to see if they know who the best people to put you in contact with would be.

All the best,  
Martha Knuth, MLIS  
Librarian

**Stephen B. Thacker CDC Library**

Office of Library Science

Office of Science

Centers for Disease Control and Prevention

Roybal Campus/Global Communications Center/ Bldg 19

1600 Clifton Road, N. E., MS H19-1

Atlanta, GA 30329

**Office:** 404.718.5375

**Email:** mto4@cdc.gov



CDC Office of Science  
QUALITY | INTEGRITY | INNOVATION

---

**From:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>

**Sent:** Thursday, April 30, 2020 6:22 PM

**To:** Honeycutt, Sally (CDC/DDPHSS/CSELS/DSEPD) <ejk6@cdc.gov>; Knuth, Martha (CDC/DDPHSS/OS/OLS) <mto4@cdc.gov>

**Subject:** RE: COVID-19 Clinical Data Analysis

Sally, thank you!

@Martha – wow! You're the mastermind behind this database, kudos to you. I've been using it, thank you! However, instead of starting from scratch in systematically combing through all of the literature, we thought we'd ask around to see if anyone has already done this for various topics, for example a scarping of literature for retrospective and prospective clinical study data on hydroxychloroquine for COVID-19.

Much appreciated, both of you!

Kind Regards,

April Inyard Alexandrow

FDA/OC/Office of Clinical Policy & Programs (OCPP)

p: 301.796.5363



---

**From:** Honeycutt, Sally (CDC/DDPHSS/CSELS/DSEPD) <ejk6@cdc.gov>  
**Sent:** Thursday, April 30, 2020 5:41 PM  
**To:** Knuth, Martha (CDC) <mto4@cdc.gov>; Alexandrow, April <April.Alexandrow@fda.hhs.gov>  
**Subject:** RE: COVID-19 Clinical Data Analysis

Hi April,

I'm sending this email to connect you to CDC Librarian Martha Knuth. Please see below for a link to her daily systematic search for all COVID-19 literature, and follow up directly with her if you'd like to collaborate.

Thanks,  
Sally

~~~~~  
Sally Honeycutt  
404.498.1917  
shoneycutt@cdc.gov

---

**From:** Robb, Melissa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B6E9F29718844A138AD798A2F0698423-ROBBM]  
**Sent:** 5/5/2020 9:25:52 AM  
**To:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Alexandrow, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae28fb4c1e044e2e9bd727f7f6a3ebb3-ALEXANDROWA]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]  
**Subject:** Discuss COVID Literature  
**Attachments:** FW: COVID-19 Clinical Data Analysis; Fw: Two more findings; Fw: COVID-19 Insights Sub-TF Call - Analysis; Fw: Lab Meeting today  
**Location:** telecon  
**Start:** 5/5/2020 12:00:00 PM  
**End:** 5/5/2020 12:30:00 PM  
**Show Time As:** Busy

**Required Attendees:** Hoffman, Allison; Alexandrow, April; Abernethy, Amy; Valo, Gina

Trying to organize everything I have seen/heard on this topic in the hopes that when we meet we can figure out plan and move forward. Some notes below.

(b)(5)

**(b)(5)**

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code):

Meeting password:

**Join meeting**

**Join by phone**

Tap to call in from a mobile device (attendees only)

+1-877-465-7975 US Toll Free

+1-210-795-0506 US Toll

Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to <http://help.webex.com>

---

**From:** Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109E347D6AC4]  
**Sent:** 5/6/2020 11:04:24 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Meeting Forward Notification: COVID-19 Drug Development Discussion  
**Location:** WebEx  
**Start:** 5/11/2020 4:30:00 PM  
**End:** 5/11/2020 5:00:00 PM  
**Recurrence:** (none)

## Your meeting was forwarded

Nguyen, Mimi has forwarded your meeting request to additional recipients.

### Meeting

COVID-19 Drug Development Discussion

### Meeting Time

Monday, May 11, 2020 4:30 PM-5:00 PM.

### Recipients

Nirosha Mahendraratnam Lederer, Ph.D.

Hoffman, Allison

Morgan Romine

Marta Wosinska, Ph.D.

Robb, Melissa

Franklin, Joseph

Nguyen, Mimi

All times listed are in the following time zone: (UTC-05:00) Eastern Time (US & Canada)

---

Sent by Microsoft Exchange Server



---

**From:** Morgan Romine [morgan.romine@duke.edu]  
**Sent:** 5/11/2020 9:01:37 AM  
**To:** Dr Mark McClellan, M.D. [mark.mcclellan@duke.edu]; Suky Warner [suky.warner@duke.edu]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Miller, Steven B. (STL) [SMiller@express-scripts.com]; WShrank@humana.com; Amy.Compton-Phillips@providence.org; Nirosha Mahendraratnam Lederer, Ph.D. [nirosha.mahendraratnam@duke.edu]; Marta Wosinska, Ph.D. [marta.wosinska@duke.edu]; Marianne Hamilton Lopez, Ph.D. [marianne.hamilton.lopez@duke.edu]; Allen, Jeff [jallen@focr.org]; Ostermann, Linda [lostermann@focr.org]; Anand.Chokkalingam@gilead.com; Robertino.Mera@gilead.com; matt.bryant@gilead.com; Brown, Jeffrey [jeff\_brown@harvardpilgrim.org]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]  
**Subject:** COVID-19 postmarket evidence efforts  
**Attachments:** 20200507\_remdesivir\_rwe overview v2.docx; Evidence Accelerator Remdesivir v2.docx  
**Location:** https://duke.zoom.us/j/91729849697 -or- dial 917 2984 9697  
**Start:** 5/11/2020 12:00:00 PM  
**End:** 5/11/2020 1:00:00 PM  
**Show Time As:** Tentative

**Recurrence:** (none)

**\*\*Updated with discussion documents\*\***

Holding time for FDA, Margolis, and outside collaborators to discuss postmarket evidence development opportunities for COVID-19 treatments.

Hoping everyone can join for part of the hour – looking forward to the discussion and will follow up with supportive materials/questions as we have them.

Thanks!  
Morgan

---

Morgan Romine is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

(b)(6)

Meeting ID: (b)(6)

One tap mobile

(b)(6)

US (Chicago)  
US (New York)

Dial by your location

+1 312 626 6799 US (Chicago)

- +1 646 876 9923 US (New York)
- +1 301 715 8592 US (Germantown)
- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)
- +1 408 638 0968 US (San Jose)

Meeting ID: **(b)(6)**

Find your local number: <https://duke.zoom.us/j/9qC0OpJAr>

Join by SIP

**(b)(6)**

Join by H.323

- 162.255.37.11 (US West)
- 162.255.36.11 (US East)
- 115.114.131.7 (India Mumbai)
- 115.114.115.7 (India Hyderabad)
- 213.19.144.110 (EMEA)
- 103.122.166.55 (Australia)
- 209.9.211.110 (Hong Kong  
China)
- 64.211.144.160 (Brazil)
- 69.174.57.160 (Canada)
- 207.226.132.110 (Japan)

Meeting ID: **(b)(6)**

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 5/11/2020 9:33:04 AM  
**To:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Allen, Jeff [jallen@focr.org]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]  
**Subject:** Fw: of interest  
**Attachments:** Freedberg Famotidine NY preprint May 2020.pdf

This keeps popping up...

---

**From:** Schnitzer, Jay J <jschnitzer@mitre.org>  
**Sent:** Monday, May 11, 2020 9:12 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** of interest

Hi Amy,  
See attached (in case you haven't seen it already).  
Famotidine is worthy of further study.  
Best,  
Jay

--

**Jay J. Schnitzer, M.D., Ph.D.**  
Vice President, Chief Technology Officer (CTO),  
Chief Medical Officer (CMO)  
The MITRE Corporation  
202 Burlington Road | Bedford, MA | 01730-1420  
Mobile: (b)(6)  
Email: [jschnitzer@mitre.org](mailto:jschnitzer@mitre.org)

---

**From:** Alexandrow, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AE28FB4C1E044E2E9BD727F7F6A3EBB3-ALEXANDROWA]  
**Sent:** 5/11/2020 10:05:35 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]  
**Subject:** [AA thoughts]: HCQ (and other) prospective trials  
**Attachments:** COVID-19\_ClinTrials\_HCQ\_Metrics\_20200428.pdf; CDC-HCQ-COVID19.xlsx

Amy,

I believe you originally asked me to work on gathering data on prospective HCQ trials and originally started accumulating information on all prospective trials involving at least HCQ (and possibly other interventions). Those raw data were the underlying input for the metrics dashboard I made back on 4/28/20 (attachment #1).

I attached the spreadsheet of raw data if you're interested (attachment #2). However, I haven't updated it since ~April 24 because the effort to track prospective trials (of all kinds) is being done on a much more sophisticated level, in particular the last link below (note you'll need your personal device, FDA firewall blocks).

Please let me know what you think of this work moving forward. Perhaps it's a weekly look at some of the work being done in the links below and a high level summary?

1. Interventions for treatment of COVID-19: a protocol for a living systematic review with network meta-analysis including individual patient data (The LIVING Project)
2. A real-time dashboard of clinical trials for COVID-19
3. (FDA Firewall blocks this, try on your personal phone or computer): [www.covid19-trials.org](http://www.covid19-trials.org)

Kind Regards,

April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



---

**From:** Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]  
**Sent:** 5/11/2020 5:45:40 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Wohl, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ee6d17fe8114d16bc6244f59d9d00b4-Alexander.W]  
**CC:** Adleberg, Jill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=247cf2d82d3f42f0a6e1be6588c29ce9-JSA]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Burns, Corey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e0cbe2d2aec44d5b389359b7ba313f1-Corey.Burns]; Colonius, Tristan

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Coll]; Feingold, Daniel  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbf8daec2f4546688eebf081f1b45eb4-Daniel.Fein]; George, Bryan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a4179c14ea4cc983edd2eee26d3e82-Bryan.Georg]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Hodnette, Jonathan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Howard, Megan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Lexer, Susan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fac3c4e96444fdbaa05383b456b7c73-Susan.Lexer]; Lockheed, Matthew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Luebke, Yasemin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Paulos, Lauren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Pennington, Caitlin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Rath, Prakash (FDA)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Schipper, Jodi  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Rosebraugh, Sydney  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21eebb94e1f34ddcbc1334acc9ca4e82-Sydney.Rose]

**Subject:** OL Reactive TPs for COVID Briefings

**Attachments:** Reactive TPs 5.11.20.docx

Attached are OL's Reactive Talking Points, updated through 5pm today.

Thank you.

**Andrew Tantillo, J.D.**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
301-796-8919 M 202-809-2989  
andrew.tantillo@fda.hhs.gov



**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 5/15/2020 6:51:16 AM  
**To:** Alexandrow, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae28fb4c1e044e2e9bd727f7f6a3ebb3-ALEXANDROWA]  
**CC:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]  
**Subject:** Re: [AA REVIEW by \*noon\* 5/15] - PDC COVID-19 Notables Newsletter [May 15, 2020]  
**Sensitivity:** Company Confidential

Hi - Thank you!

(b)(5)

## Welcome — RECOVERY Trial

Letters from the Chief Medical Officers. The Chief Medical Officers of England, Wales, Scotland and Northern Ireland, and the NHS Medical Director, have written to all doctors strongly encouraging participation in the national randomised trials in COVID-19 of which RECOVERY is one.

[www.recoverytrial.net](http://www.recoverytrial.net)

5.

---

**From:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>  
**Sent:** Thursday, May 14, 2020 3:47 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Robb, Melissa <Melissa.Robb@fda.hhs.gov>  
**Subject:** [AA REVIEW by \*noon\* 5/15] - PDC COVID-19 Notables Newsletter [May 15, 2020]

Amy – Please review for tomorrow’s distribution. In particular, please review Sections I and II to make sure these are the things you want to send out. I recommend (b)(5)

(b)(5)

Will BCC everyone with a Cc to you this week.

May 15, 2020

**PDC COVID-19 NOTABLES NEWSLETTER**

**(b)(5)**



**(b)(5)**

**(b)(5)**

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 5/15/2020 6:52:18 AM  
**To:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Alexandrow, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae28fb4c1e044e2e9bd727f7f6a3ebb3-ALEXANDROWA]  
**CC:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]  
**Subject:** Re: RE: PDC CMAG Newsletter  
**Attachments:** NEJM JAMA 5-14-20.pptx; nejmoa2012410.pdf; jama\_rosenberg\_2020\_oi\_200055.pdf

Thank you.

@April - for those not already in the Notables, please add the new ones in the list below. Also, we should pull the Israeli database study & convalescent plasma safety data mentioned below and turn it into a few slides for our summary review (for our internal review & potentially CMAG; not really the notables).

The ppt with the summaries of the JAMA and NEJM papers is attached.

Can we make sure that both the JAMA and NEJM papers are links in the notables? In terms of the ppt - I am not sure if we should include it or not. Can we discuss on the PDC call, @Melissa? We should also think through sending it to CMAG (with the papers).

Thanks!

A

---

**From:** Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>  
**Sent:** Thursday, May 14, 2020 5:11 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Alexandrow, April <April.Alexandrow@fda.hhs.gov>  
**Cc:** Robb, Melissa <Melissa.Robb@fda.hhs.gov>  
**Subject:** FW: RE: PDC CMAG Newsletter

Some additional articles for consideration for this week's notables.

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Thursday, May 14, 2020 5:01 PM  
**To:** Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>  
**Subject:** RE: PDC CMAG Newsletter

Hi. A few articles for consideration

- An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study
- Association of Treatment With Hydroxychloroquine or Azithromycin With In-Hospital Mortality in Patients With COVID-19 in New York State

- Circulating plasma concentrations of angiotensin-converting enzyme 2 in men and women with heart failure and effects of renin-angiotensin-aldosterone inhibitors
- Continuous hydroxychloroquine or colchicine therapy does not prevent infection with SARS-CoV-2: Insights from a large healthcare database analysis.
- Repurposing of chloroquine and some clinically approved antiviral drugs as effective therapeutics to prevent cellular entry and replication of coronavirus.
- Triple combination of interferon beta-1b, lopinavir-ritonavir, and ribavirin in the treatment of patients admitted to hospital with COVID-19: an open-label, randomised, phase
- Early Safety Indicators of COVID-19 Convalescent Plasma in 5,000 Patients

**From:** Ip, Andrew M.D. [Andrew.Ip@hackensackmeridian.org]  
**Sent:** 5/16/2020 4:25:47 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Goldberg, Stuart M.D. [Stuart.Goldberg@hackensackmeridian.org]  
**Subject:** JAMA proof manuscript  
**Attachments:** JAMA\_proof.pdf; Supplement - statistical output.pdf

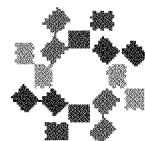
This message was sent securely using Zix®

Dear Dr. Abernethy

Please see our attached JAMA manuscript proof and supplement

Thank you

Andrew Ip, MD, MS  
Lymphoma Division, John Theurer Cancer Center  
Division of Outcomes and Value Research



Hackensack  
Meridian Health



John Theurer  
Cancer Center

*Consortium Member of*

Georgetown | Lombardi  
COMPREHENSIVE CANCER CENTER



92 Second Street  
Hackensack NJ 07601  
t.551-996-1833 | f.551-996-0920  
Andrew.ip@hackensackmeridian.org



A Cancer Center designated by the  
National Cancer Institute

This message was secured by Zix®.

**From:** Nguyen, Mimi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=806B10EA0D144541B48BEED0B5E35796-MIMI.NGUYEN]  
**Sent:** 5/18/2020 4:19:39 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; 'Mark Shapiro' [mshapiro@xcures.com]; Mika Newton [mika@xcures.com]; 'Carla Rodriguez' [crodriguezwatson@reaganudall.org]; 'Amar Bhat' [abhat@reaganudall.org]; 'Allen, Jeff' [jallen@focr.org]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; 'Sae Yamada' [syamada@xcures.com]; Glenn Kramer [gkramer@xcures.com]; 'awasserman@xcures.com' [awasserman@xcures.com]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Subject:** Xcures COVID Discussion with RUF & FDA  
**Attachments:** Re: COVID-19 Evidence Accelerator Collaborative Meeting; Prelim Beat19 results for FOCR-FDA v05\_28\_2020.pdf; Xcures COVID Discussion with RUF & FDA (Slide Presentation); Re: COVID-19 Evidence Accelerator Collaborative Meeting; Prelim Beat19 results for FOCR-FDA v05\_28\_2020.pdf; Xcures COVID Discussion with RUF & FDA (Slide Presentation)  
**Location:** virtual  
**Start:** 5/29/2020 4:00:00 PM  
**End:** 5/29/2020 5:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** 'Mark Shapiro'; Mika Newton; 'Carla Rodriguez'; 'Amar Bhat'; 'Allen, Jeff'; Tunis, Sean; Robb, Melissa; Roe, Laura; 'Sae Yamada'; Glenn Kramer; awasserman@xcures.com



Prelim Beat19 results for FOCR...



Prelim Beat19 results for FOCR...

Please contact @Nguyen, Mimi to update this invite.



Xcures COVID Discussion with ...

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code) (b)(6)

088

Meeting password: (b)(6)

## Join meeting

### Join by phone

Tap to call in from a mobile device (attendees only)

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

[Global call-in numbers](#) | [Toll-free calling restrictions](#)

If you are a host, [go here](#) to view host information.

Need help? Go to <http://help.webex.com>



Xcures COVID  
Discussion with ..



Re: COVID-19  
Evidence Accele...



Re: COVID-19  
Evidence Accele...

**From:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Sent:** 5/18/2020 4:19:39 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; 'Mark Shapiro' [mshapiro@xcures.com]; Mika Newton [mika@xcures.com]; 'Carla Rodriguez' [crodriguezwatson@reaganudall.org]; 'Amar Bhat' [abhat@reaganudall.org]; 'Allen, Jeff' [jallen@focr.org]; Tunis, Sean [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b43fc479bef5419c96c5e06b9de332f2-Robert.Tuni]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; 'Sae Yamada' [syamada@xcures.com]; Glenn Kramer [gkramer@xcures.com]; awasserman@xcures.com  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]

**Subject:** Xcures COVID Discussion with RUF & FDA

**Attachments:** Re: COVID-19 Evidence Accelerator Collaborative Meeting; Prelim Beat19 results for FOCR-FDA v05\_28\_2020.pdf; Xcures COVID Discussion with RUF & FDA (Slide Presentation)

**Location:** virtual

**Start:** 5/29/2020 4:00:00 PM

**End:** 5/29/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** 'Mark Shapiro'; Mika Newton; 'Carla Rodriguez'; 'Amar Bhat'; 'Allen, Jeff'; Tunis, Sean; Robb, Melissa; Roe, Laura; 'Sae Yamada'



Prelim Beat19 results for FOCR...



Xcures COVID Discussion with ...

Please contact [Mimi.Nguyen@xcures.com](mailto:Mimi.Nguyen@xcures.com) to update this invite.



Re: COVID-19 Evidence Accele..

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code) (b)(6)

(b)(6)

Meeting password: (b)(6)



## Join meeting

### Join by phone

Tap to call in from a mobile device (attendees only)

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

Need help? Go to <http://help.webex.com>

---

**From:** Nguyen, Mimi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=806B10EA0D144541B48BEED0B5E35796-MIMI.NGUYEN]  
**Sent:** 5/18/2020 5:16:42 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Hunt, Michie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7815b5291a944498653374dada35d91-HUNTM]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Alexandrow, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae28fb4c1e044e2e9bd727f7f6a3ebb3-ALEXANDROWA]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Schick, Andreas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce65e11cf29b486b99da49528c348cd8-Andreas.Sch]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Vasisht, Kaveeta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=829ef402d6284b4aab60db92ebada1dd-VASISHTK]; Chai, Grace P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f664df5cc254e4daaaf3a15de70f4d6-CHAIP]; Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]  
**CC:** Dal Pan, Gerald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=273ac18eca2349d6996990ea22ab1a5b-DALPANG]; Budashewitz, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38f690da6364b3283d1940fb216e3ee-Philip.Buda]; Jung, Connie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3977c42d362d4d50a219c6c417fd24c6-JUNGCC]; Verbois, Leigh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f07128d11cda4bf1b48e4110cddb9fbc-VERBOISL]  
**Subject:** RE: CMAG - Drug Shortages  
**Attachments:** hydroxychloroquine distribution presentation.pptx

Good evening,

Enclosed is Grace's slides from today's discussion about returned products. Please note, this presentation does contain confidential information so please do not distribute.



hydroxychloroqui..  
distribution prese...

Thank you.

Cheers,  
Mimi

-----Original Appointment-----

**From:** Nguyen, Mimi **On Behalf Of** Abernethy, Amy

**Sent:** Friday, April 10, 2020 8:49 AM

**To:** Hunt, Michie; Abernethy, Amy; Franklin, Joseph; Valo, Gina; Hoffman, Allison; Nguyen, Mimi; Alexandrow, April;

Throckmorton, Douglas C; Schick, Andreas; Lutter, Randall; Vasisht, Kaveeta; Chai, Grace P; Robb, Melissa  
**Cc:** Dal Pan, Gerald; Budashewitz, Philip; Jung, Connie; Verbois, Leigh  
**Subject:** CMAG - Drug Shortages  
**When:** Monday, May 18, 2020 3:30 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** WebEx

**Agenda:**

Presentation from Grace: Returned product - regional excess supply and signals of needs for hydroxychloroquine

Please contact [@Nguyen, Mimi](#) to update or change this meeting invite.

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): **(b)(6)**

**(b)(6)**

Meeting password: **(b)(6)**

[Join meeting](#)

**Join by phone**

Tap to call in from a mobile device (attendees only)

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

Need help? Go to <http://help.webex.com>

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 5/18/2020 10:04:24 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** HCQ for mild/mod COVID-19  
**Attachments:** Outpatient HCQ Data 5-18-20.pdf

Hi Steve,

As you and I discussed, there are many questions about HCQ for mild/mod COVID-19 and whether it is safe and effective in this setting.

You wanted to know: "Can real-world data and real-world evidence (RWE/RWD) help us here? What would it take to resolve this question quickly?"

In réponse, I have been working to identify what might be possible. Please find the attached slide deck that summarizes my findings. In the deck I highlight a few potential data sources that I am chasing down.

Importantly, as I look across the literature (b)(5)

(b)(5)

Please let me know if you have any questions.

Thanks,

Amy

Amy P. Abernethy, MD PhD  
Principal Deputy Commissioner  
Acting Chief Information Officer  
US Food & Drug Administration

Mobile: (b)(6)  
Email: amy.abernethy@fda.hhs.gov

---

**From:** Hoffman, Allison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEED30BE6A004DD29AC6C7F8EBCADBC5-ALLISON.HOF]  
**Sent:** 5/20/2020 8:30:35 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]  
**Subject:** Meeting prep for CERSI Scientific Advisory Board May 21 2020  
**Attachments:** Meeting prep sheet CERSI Scientific Advisory Board May 21 2020.docx

Hi Amy,

Please see the attached meeting prep for tomorrow's (5/21/2020) virtual talk at the CERSI Scientific Advisory Board meeting. It is 5-10 min of remarks (based on the BioCentury interview talking points) followed by 5-10 min of QA.

Allison

---

**From:** Martin, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E814116F721841D6BD9C211787773F55-MARTIND]  
**Sent:** 5/20/2020 9:39:46 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** FW: FDA MyStudies going live for COVID-19 - FYI from April approval  
**Attachments:** FDA-Guidance-Conduct-of-Clinical-Trials-of-Medica-Products-During-COVID-19-Pandemic.pdf

Amy,

This is the email chain that preceded Apples approval of the app within 24 hours after it was submitted later in the month. I explained that with FDA-Catalyst/Sentinel, “private sector data stays in the private sector” and FDA MyStudies is not on the FDA network and does not have an FDA developer account.

David

---

**From:** Martin, David  
**Sent:** Monday, April 06, 2020 11:07 AM  
**To:** chris.tan@apple.com; Divya Nag <dnag@apple.com>  
**Cc:** Mark Malone <mgm@apple.com>; smravca@apple.com; Reynolds, Juliane <Juliane\_Reynolds@harvardpilgrim.org>; Dianne Paraoan <Dianne.Paraoan@fda.hhs.gov>  
**Subject:** RE: FDA MyStudies going live for COVID-19

Chris,

Thanks for commenting on the core issue which is the Apple developer account policy. The FDA developer account is for FDA network systems and cannot be used because this is not an FDA network system.

Harvard Pilgrim is FDA’s prime contractor for the FDA-Catalyst system (<https://www.sentinelinitiative.org/fda-catalyst>) in which FDA partners with private sector partners to sponsor studies with public health or regulatory implications. It is specifically designed not to interact with the FDA network so private sector data stays in the private sector.

Due to the COVID-19 pandemic we are planning to rapidly launch a version of FDA MyStudies that will have FDA Badging. This App will serve as a gateway that can be used to enable principal investigators to obtain signed informed consent from patients and preserve this digital record appropriately. Page 15 and 16 of the attached FDA Guidance (Question 10) describes the problem we are trying to solve for healthcare facilities engaged in these trials. The FDA branding is important so front line healthcare staff can potentially return to the same gateway app for multiple trials that might run in their institution.

Please place me in contact with staff at Apple who can address whether there is an App Store policy that prevents this and if so, how we can address the issue. We don’t want to end up in a situation where only patients with Android operating systems can use the App and patients with Apple phones need to use the paper and witness based process.

Thanks in advance for offering to assist with expediting the publishing process, and we will send the AppID when we have it.

David

---

**From:** chris.tan@apple.com <chris.tan@apple.com>

**Sent:** Tuesday, March 24, 2020 2:38 PM

**To:** Divya Nag <dnag@apple.com>

**Cc:** Martin, David <David.Martin@fda.hhs.gov>; Mark Malone <mgm@apple.com>; smravca@apple.com; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Quinto, Kenneth <Kenneth.Quinto@fda.hhs.gov>; Reynolds, Juliane <Juliane\_Reynolds@harvardpilgrim.org>

**Subject:** Re: FDA MyStudies going live for COVID-19

Could we start with the AppID? The 9 or 10 digit number associated with the app.

I can't speak to exceptions but we can certainly expedite.

I believe the FDA has an account why not publish it there if that's who actually owns the app.

~Chris

On Mar 24, 2020, at 11:29 AM, Divya Nag <dnag@apple.com> wrote:

Hi David,

Looping in Chris and Mark from the Apple end to help look into this for you.

Divya

On Mar 24, 2020, at 7:26 AM, Martin, David <David.Martin@fda.hhs.gov> wrote:

Sam and Divya,

We are planning to rapidly launch a version of FDA MyStudies that will have FDA Badging. (See below)

This App will be used to help pharmaceutical sponsors complete COVID-19 clinical trials.

*Time is of the essence, and we need an exception to Apple policy which will enable FDA's contractor, Harvard Pilgrim, to place this app in the Apple App store without an FDA developer account. The developer account will be from Harvard Pilgrim.*

*We also need Apple to prioritize the Harvard Pilgrim request so it does not take the standard two weeks for approval.*

You can contact me at (b)(6) if you have questions about the FDA effort. If you don't reach me and need an immediate response then please call Ken Quinto at (b)(6). If you have specific questions about the developer account from Harvard Pilgrim, please contact Juliane Reynolds at (b)(6).

Thanks in advance,

David

**David Martin, MD, MPH**

*Captain, U.S. Public Health Service*

Associate Director for Real World Evidence Analytics  
Office of Medical Policy, Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
Tel: 240-402-8710  
david.martin@fda.hhs.gov

<image003.png>

<image016.jpg>

<image017.jpg>

<image018.jpg>

<image019.jpg>

<image020.jpg>

<image021.jpg>

COVID19 MyStudies



**From:** Dreyer, Nancy [Nancy.Dreyer@iqvia.com]  
**Sent:** 5/20/2020 10:50:28 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Mack, Christina [Christina.Mack@iqvia.com]; Reynolds, Matthew [matthew.reynolds@iqvia.com]; Beggs, Christopher [Christopher.Beggs@iqvia.com]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** some options for (b)(4)  
**Attachments:** IQVIA.ideas; (b)(4); 19May2020.pdf

Dear Amy,

Pursuant to our discussion last week, we put some ideas together for how we could help the FDA look at (b)(4)

(b)(4)

Please let me know if you like to discuss. We'd be happy to set up a time to review at your convenience.

Best regards,  
Nancy

**Nancy A Dreyer, PhD, MPH, FISPE, Fellow DIA**  
Chief Scientific Officer and Senior Vice President  
Head, Center for Advanced Evidence Generation  
IQVIA Real World Solutions



201 Broadway, 5<sup>th</sup> floor  
Cambridge, MA 02139 USA  
O: +1617 715 6810 | M: (b)(6) | E: Nancy.Dreyer@IQVIA.com

Visit [www.helpstopCOVID19.com](http://www.helpstopCOVID19.com) for community reporting about symptoms, possible preventives & treatments

**IMPORTANT - PLEASE READ:** This electronic message, including its attachments, is CONFIDENTIAL and may contain PROPRIETARY or LEGALLY PRIVILEGED or PROTECTED information and is intended for the authorized recipient of the sender. If you are not the intended recipient, you are hereby notified that any use, disclosure, copying, or distribution of this message or any of the information included in it is unauthorized and strictly prohibited. If you have received this message in error, please immediately notify the sender by reply e-mail and permanently delete this message and its attachments, along with any copies thereof, from all locations received (e.g., computer, mobile device, etc.). To the extent permitted by law, we may monitor electronic communications for the purposes of ensuring compliance with our legal and regulatory obligations and internal policies. We may also collect email traffic headers for analyzing patterns of network traffic and managing client relationships. For further information see: <https://www.iqvia.com/about-us/privacy/privacy-policy>. Thank you.

---

**From:** Franklin, Joseph [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACE8AF0979A847C59EA26C37C4904883-JOSEPH.FRAN]  
**Sent:** 5/20/2020 12:54:42 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]  
**Subject:** FW: PDC-OCP-OTS Discussion  
**Attachments:** Drug evaluation for COVID-19 using Real-World Data-May 20.pptx

Amy: Melissa and I talked about the presentation from CDER/OTS this morning.

(b)(5)

(b)(5)

(b)(5)

Let us know if you have concerns.

Cc'ing Laura for awareness.

**From:** Robb, Melissa <Melissa.Robb@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:41 AM  
**To:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** FW: PDC-OCP-OTS Discussion

**From:** Liu, Qi (CDER) <Qi.Liu@fda.hhs.gov>  
**Sent:** Tuesday, May 19, 2020 9:13 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>; Roe, Laura <Laura.Roe@fda.hhs.gov>; Buckman-Garner, ShaAvhrée <ShaAvhree.Buckman-Garner@fda.hhs.gov>; Huang, Ruihao \* <Ruihao.Huang@fda.hhs.gov>; Charpignon, Marie-Laure \* <Marie-Laure.Charpignon@fda.hhs.gov>; Wang, Yaning <Yaning.Wang@fda.hhs.gov>; Zhu, Hao <Hao.Zhu@fda.hhs.gov>; Huang, Shiew Mei <ShiewMei.Huang@fda.hhs.gov>; Zineh, Issam <Issam.Zineh@fda.hhs.gov>  
**Cc:** Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>  
**Subject:** RE: PDC-OCP-OTS Discussion



Drug evaluation for  
COVID-19 using ...

Dear all,

We are looking forward to our meeting tomorrow. To facilitate the discussion, our fellows Ruihao and Marie will give a short presentation. Attached please find the slides.

Thanks and best regards,  
Qi

-----Original Appointment-----

**From:** Abernethy, Amy

**Sent:** Monday, May 18, 2020 5:56 PM

**To:** Abernethy, Amy; Robb, Melissa; Rocca, Mitra; Roe, Laura; Buckman-Garner, ShaAvhrée; Huang, Ruihao \*; Charpignon, Marie-Laure \*; Liu, Qi (CDER); Wang, Yaning; Zhu, Hao; Huang, Shiew Mei; Zineh, Issam

**Cc:** Nguyen, Mimi

**Subject:** PDC-OCP-OTS Discussion

**When:** Wednesday, May 20, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** virtual

<< Message: RE: OTS/OCP >>

Please contact [@Nguyen, Mimi](#) to update this invite.

-- Do not delete or change any of the following text. --

**When it's time, join your Webex meeting here.**

Meeting number (access code): **(b)(6)**

**(b)(6)**

Meeting password: **(b)(6)**

[Join meeting](#)

**Join by phone**

Tap to call in from a mobile device (attendees only)

+1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, [go here](#) to view host information.

Need help? Go to <http://help.webex.com>

---

**From:** Alexandrow, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AE28FB4C1E044E2E9BD727F7F6A3EBB3-ALEXANDROWA]  
**Sent:** 6/5/2020 1:45:42 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]  
**Subject:** [AA Review by 6/11/20] - CDC Update 06/05/20  
**Attachments:** 2020 06 05 Science Update - FINAL.pdf

For consideration for the 6/12/20 notables.

Kind Regards,

April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 6/10/2020 10:15:38 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]  
**CC:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**Subject:** For Reference @ Kitchen Cabinet, 6/10  
**Attachments:** JCC Daily Brief 10JUN2020.pdf

Good morning Kitchen Cabinet team –

Dr. Hahn has requested the distribution of the attached PDF (*JCC Daily Brief 10 JUN 2020*) which was provided to Dr. Hahn for this morning's AMA Daily COVID 19 Synch.

Thank you,  
Frank

-----Original Appointment-----

**From:** Sheehy, Janice **On Behalf Of** Hahn, Stephen

**Sent:** Tuesday, March 17, 2020 4:54 PM

**To:** Lenihan, Keagan; Hahn, Stephen; Abernethy, Amy; Shah, Anand; Rom, Colin; Amin, Stacy; Yiannas, Frank; Abram, Anna

**Subject:** Kitchen Cabinet

**When:** Wednesday, June 10, 2020 4:15 PM-4:45 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** 1-877-465-7975, (b)(6)

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 6/15/2020 5:37:39 PM  
**To:** Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]  
**Subject:** Fw: Cyclosporin A and analogs  
**Attachments:** Cyclosporin and Cyclosporin Analogs to Treat COVID.docx; CsA in COVID Italian Study.pdf; COV2 inhibit by CsA.pdf; CsA for cytokine storm.pdf

FYI

(b)(5)

---

**From:** Rosenberg, Amy <Amy.Rosenberg@fda.hhs.gov>  
**Sent:** Sunday, June 7, 2020 2:45 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** Cyclosporin A and analogs

Dear Amy and Allison

Another agent that should be assessed for chronic treatment and that has antiviral activity as well as immunosuppressive properties, for which it is primarily used, is Cyclosporin A and FK506 (both calcineurin inhibitors). Non-immune suppressive analogs have been developed and one rather extensively tested (not for COVID-19) but thus far none have been approved.

Would certainly inquire regarding these two (Cyclosporin A and FK506) approved and widely used agents.

All the best  
Amy

---

**From:** Andrews, Raymond [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CA67B5A5685245DCBB1305065A59876C-RAYMOMD.AND]  
**Sent:** 7/8/2020 11:25:47 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Roe, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=536d87b3d3e74273a6d2db52fa8c170b-Laura.Roe]; Valo, Gina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a138e029c7147958d3764ce9bd4b745-Gina.Valo]; Allen, Jeff [jallen@focr.org]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Re: Parallel analysis rough slides  
**Attachments:** Parallel analysis draft slides-0707.pdf

Attached!

---

**From:** "Andrews, Raymond" <RJ.Andrews@fda.hhs.gov>  
**Date:** Wednesday, July 8, 2020 at 8:24 AM  
**To:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Cc:** "Roe, Laura" <Laura.Roe@fda.hhs.gov>, "Valo, Gina" <Gina.Valo@fda.hhs.gov>, "Allen, Jeff" <jallen@focr.org>, "Franklin, Joseph" <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: Parallel analysis rough slides

Good Amy. Weave me in as you can.

Jeff & Joe: attached is my first stab from late last night. In particular I had difficulty

(b)(5)

(b)(5)

Feel free to reach out if you want to discuss 1:1 today. -RJ

---

**From:** "Abernethy, Amy" <Amy.Abernethy@fda.hhs.gov>  
**Date:** Wednesday, July 8, 2020 at 8:20 AM  
**To:** "Andrews, Raymond" <RJ.Andrews@fda.hhs.gov>  
**Cc:** "Roe, Laura" <Laura.Roe@fda.hhs.gov>, "Valo, Gina" <Gina.Valo@fda.hhs.gov>, "Allen, Jeff" <jallen@focr.org>, "Franklin, Joseph" <Joseph.Franklin@fda.hhs.gov>  
**Subject:** Re: Parallel analysis rough slides

Oh this is fun. I am looking forward to more conversation later today. I can talk after 1:30p ET (sporadically). I am adding Jeff Allen to this email trail as well as Joe. I have a lot of ideas but really like the general direction.

Take care,

A

---

**From:** Andrews, Raymond <RJ.Andrews@fda.hhs.gov>  
**Sent:** Wednesday, July 8, 2020 3:26 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Roe, Laura <Laura.Roe@fda.hhs.gov>; Valo, Gina <Gina.Valo@fda.hhs.gov>  
**Subject:** Parallel analysis rough slides

Amy: attached is a mix of graphics. Take it as a menu of ingredients to use for the narrative flow, not quite yet a narrative flow itself.

+NYT headlines about HCQ just for fun (less those related to Brazil). We should talk tomorrow. -RJ



**From:** Wilcox, Kelly (HHS/ASFR) [Kelly.Wilcox@hhs.gov]  
**Sent:** 7/10/2020 7:53:53 AM  
**To:** Berger, Dan P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f38bccfea694a5a8cb66cef14cc3eca-HHS-Dan.Ber]; Bernier, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64c31d7adc964194be5b8c755f6bc9b3-HHS-Michael]; Cheung, Douglas G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e5bdf7748314489a03a6193ba01735a-HHS-Douglas]; Rafiq, Sana [Rafiq.Sana@bcg.com]; Larkin, Maggie [Larkin.Maggie@bcg.com]; Rossi, Alvaro [Rossi.Alvaro@bcg.com]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]; White, Raeshawn D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c20578384893416a92e62978e78250b4-HHS-Raeshaw]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Valentine, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9555e00b1972472c81b4f89fb68428f3-KValenti]

**Subject:** FDA KPIs for Programs Supporting Diagnostics, Therapeutics and Vaccines

**Attachments:** 200710\_COVID-19 Performance KPI Discussion\_FDA.pptx

**Location:** Webex

**Start:** 7/10/2020 8:15:00 AM

**End:** 7/10/2020 9:00:00 AM

**Show Time As:** Tentative

**Required Attendees:** Berger, Dan (HHS/ASFR); Bernier, Michael (HHS/ASFR); Cheung, Douglas (OS/IOS); Rafiq, Sana; Larkin, Maggie; Rossi, Alvaro; Cabezas, Miriam (HHS/ASFR); White, RaeShawn (OS/ASFR); Nguyen, Mimi (FDA/CDRH); Franklin, Joseph (FDA/OC); Abernethy, Amy (FDA/OC); Valentine, Keith (FDA/OC)

We have received a request to delay this meeting by 15 minutes.

Updated with materials

\*\*\*DO NOT DELETE OR CHANGE ANY OF THE TEXT BELOW THIS LINE\*\*\*

Kelly Wilcox has scheduled this WebEx meeting.

FDA KPIs for Programs Supporting Diagnostics, Therapeutics and Vaccines

Host: Kelly Wilcox

When it's time, start or join the WebEx meeting from here:

(b)(6)

Access Information

Meeting Number: (b)(6)

Meeting Password: (This meeting does not require a password.)

Audio Connection

**(b)(6)** Meeting Server Main Number)

Access Code:

**(b)(6)**

Hosts, need your host access code or key? Go to the meeting information page:  
**(b)(6)**

Delivering the power of collaboration  
The meetingserver.hhs.gov team

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 7/10/2020 11:16:28 AM  
**To:** Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

FYI

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Friday, July 10, 2020 11:00 AM  
**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

-----Original Message-----

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines [REDACTED] (b)(6)  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines [REDACTED] (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

**Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Alexandrow, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AE28FB4C1E044E2E9BD727F7F6A3EBB3-ALEXANDROWA]  
**Sent:** 7/10/2020 11:24:21 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Subject:** AA Review by 7/13 before Noon for PDC Notables  
**Attachments:** 2020 07 07 Science Update\_FINAL.pdf; 2020 07 10\_ Science Update\_FINAL.pdf

For Monday's PDC Notables

Kind Regards,

April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



---

**From:** Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]  
**Sent:** 7/10/2020 11:26:05 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:18 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Amy – Did Steve talk to you about this?

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Friday, July 10, 2020 11:00 AM  
**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

-----Original Message-----

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines <(b)(6)>  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines



## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/10/2020 11:41:38 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Thanks

(b)(5)

(b)(5)

I think they are also flexible on the day.

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:29 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi - No, he didn't mention it. It will need to go through Ethics and internal review; Allison & Joe can help with that. I know that I can't do 4pm on 7/16, but might be able to do 4:15p; Mimi can help to sort it out.

A

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:18 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Amy – Did Steve talk to you about this?

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Friday, July 10, 2020 11:00 AM  
**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

-----Original Message-----

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines; (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Hoffman, Allison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEED30BE6A004DD29AC6C7F8EBCADBC5-ALLISON.HOF]  
**Sent:** 7/10/2020 2:30:30 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

This has been cleared by ethics.

allison

---

**From:** Hareid, Jonathan <Jonathan.Hareid@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:29 PM  
**To:** Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Allison,

(b)(5)

Regards,

**Jonathan Hareid**  
*Regulatory Counsel*

Office of Operations  
Office of Ethics and Integrity  
U.S. Food and Drug Administration  
301-796-8895  
Jonathan.Hareid@fda.hhs.gov



---

**From:** Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 12:00 PM  
**To:** Hareid, Jonathan <Jonathan.Hareid@fda.hhs.gov>  
**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Jon,

(b)(5)

Thanks,

Allison

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

-----Original Message-----

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.



**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/10/2020 2:34:39 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Pls hold on scheduling this, trying to make it work with SH. Sorry for the back and forth!

---

**From:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:29 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi - No, he didn't mention it. It will need to go through Ethics and internal review; Allison & Joe can help with that. I know that I can't do 4pm on 7/16, but might be able to do 4:15p; Mimi can help to sort it out.

A

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:18 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Amy – Did Steve talk to you about this?

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Friday, July 10, 2020 11:00 AM  
**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Sent:** Wednesday, July 8, 2020 1:09 PM

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

-----Original Message-----

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Steve Daines (b)(5)

**Sent:** Wed, Jul 8, 2020 9:30 am

**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 7/12/2020 12:43:04 PM  
**To:** Alexandrow, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae28fb4c1e044e2e9bd727f7f6a3ebb3-ALEXANDROWA]  
**CC:** Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]  
**Subject:** Re: AA Review by 7/13 before Noon for PDC Notables  
**Attachments:** 2020 07 10\_ Science Update\_FINAL.pdf; 2020 07 07 Science Update\_FINAL.pdf

Please see attached

---

**From:** Alexandrow, April <April.Alexandrow@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:24 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Nguyen, Mimi <Mimi.Nguyen@fda.hhs.gov>  
**Subject:** AA Review by 7/13 before Noon for PDC Notables

For Monday's PDC Notables

Kind Regards,  
April Inyard Alexandrow  
FDA/OC/Office of Clinical Policy & Programs (OCPP)  
p: 301.796.5363



---

**From:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Sent:** 7/13/2020 6:10:36 PM  
**To:** Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** Fw: Outpatient HCQ  
**Attachments:** outpatient HCQ draft one.docx; ATT00001.htm

I will be reviewing in detail on the plane. For discussion.

---

**From:** Goldberg, Stuart M.D. <Stuart.Goldberg@hackensackmeridian.org>  
**Sent:** Monday, July 13, 2020 5:56 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Ip, Andrew M.D. <Andrew.Ip@hackensackmeridian.org>  
**Subject:** Outpatient HCQ

This message was sent securely using Zix®

Hi. Sorry for the delay but we were focused on our tocilizumab manuscript revisions this past week.

Attached is a near final manuscript on hydroxychloroquine in the outpatient setting. It shows that HCQ early may prevent progression requiring hospitalization. Given the importance of the findings we had the (b)(4) statistical group run several different propensity models which are all concordant. We lost significance when restricted to only patients with self reported fever cough or dyspnea but the KM plot never cross and we suspect this is a power issue.

Would be nice to confirm by an insurance company that knows how many prescriptions for hydroxychloroquine and how many hospitalizations.

We would welcome any comments. Hope to submit this week

Stuart Goldberg and Andrew Ip

---

This message was secured by Zix®

---

**From:** Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]  
**Sent:** 7/16/2020 8:53:20 AM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Wohl, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ee6d17fe8114d16bc6244f59d9d00b4-Alexander.W]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]  
**CC:** Adleberg, Jill [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=247cf2d82d3f42f0a6e1be6588c29ce9-JSA]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Colonius, Tristan



---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b3590c046734a2e928858bd579ed852-Tristan.Coll]; Feingold, Daniel  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbf8daec2f4546688eebf081f1b45eb4-Daniel.Fein]; George, Bryan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a4179c14ea4cc983edd2eee26d3e82-Bryan.Georg]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Hodnette, Jonathan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Howard, Megan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Lexer, Susan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fac3c4e96444fdbaa05383b456b7c73-Susan.Lexer]; Lockheed, Matthew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2fe9a22e8f940fa8761fad18ef37dd0-Matthew.Loc]; Luebke, Yasemin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Paulos, Lauren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Pennington, Caitlin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Rath, Prakash (FDA)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Schipper, Jodi  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Rosebraugh, Sydney  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21eebb94e1f34ddcbc1334acc9ca4e82-Sydney.Rose]; Luebke, Yasemin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Santos, Marissa  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f87994e4e1a4409acb2fa047c3f3f1b-Macandog]

**Subject:** OL Reactive TPs for COVID Briefings

**Attachments:** Reactive TPs 7.15.20.docx

Attached are OL's Reactive Talking Points, updated through yesterday.

Thank you.

**Andrew Tantillo, J.D.**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
301-796-8919 M (b)(6)  
andrew.tantillo@fda.hhs.gov



**From:** clogue@deloitte.com [clogue@deloitte.com]  
**Sent:** 7/27/2020 10:50:17 AM  
**To:** Gregurick, Susan K (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f45bb85888c448fbd4ea91e5b3d9a86-HHS-susan.g]; Brennan, Patti F (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb26df910bc248c29413116e2bf67cdf-HHS-patti.b]; Rutter, Joni L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a90497bad684a6b81166a82a65e76c3-HHS-joni.ru]; Warren A Kibbe, Ph.D. [warren.kibbe@duke.edu]; Logue, Connor [clogue@deloitte.com]; Martinez, Aracely [aracmartinez@deloitte.com]; etopol@scripps.edu; mgrubel@scripps.edu; lesley.curtis@duke.edu; Hripcsak, George M. [gh13@cumc.columbia.edu]; chute@jhu.edu; jguinney@gmail.com; robertcaliff@verily.com; ahalt@renci.org; Michael, Samuel G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ad2151380984963ad2564bbf7c8b6ae-HHS-michael]; Robert Grossman [robert.grossman@uchicago.edu]; jessie.tenenbaum@duke.edu; lola.fayanju@duke.edu; haendel@ohsu.edu; Thomson, Alastair A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b22ebdcb9454ba8b28d2e63cfe5367b-HHS-alastai]; melissa@tislab.org; john.wilbanks@sagebase.org; craig.hayn@nih.gov; Judy Murphy [murphyja@us.ibm.com]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tartakovsky, Mike (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=341c4ec53f944a2abf3c7c16832f1c13-HHS-MTARTAK]; Denny, Joshua C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d03c21bbf343fd8a552fdc361073a8-HHS-joshua.]; Guidry Auvil, Jaime M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c153c9ae7b624406a760cea13035d0d0-HHS-jaime.g]; Robert Grossman [rgrossman1@uchicago.edu]; elisabeth1@uchicago.edu  
**CC:** Tenenbaum, Jessie [jessie.tenenbaum@dhhs.nc.gov]; Hayn, Craig M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd3b77ce904438eb368c3d2f0e6978d-HHS-haync-m]  
**Subject:** NIH Workshop for Jumpstarting Clinical Data Access to COVID-19 Research: Pre-Meeting Walkthrough  
**Attachments:** Workshop Run of Show 7.27.docx; Agenda7.26v2.pptx; Jumpstart Workshop Use Cases 7.27.pptx; Workshop Slides 7.27.pntx  
**Location:** (b)(6)  
**Start:** 7/27/2020 11:00:00 AM  
**End:** 7/27/2020 11:45:00 AM  
**Show Time As:** Tentative  
**Recurrence:** (none)



[Join Meeting](#)

Document: 475055

## Join by Telephone

Dial:

US: +1 929 436 2866 or +1 669 900 6833

Meeting ID:

(b)(6)

Password:

International numbers

Zoom technology includes options for recording a meeting. If a meeting is being recorded, an audio and/or visual warning will be provided when you join a recorded meeting. A warning will also be provided if recording commences after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

Deloitte refers to a Deloitte member firm, one of its related entities, or Deloitte Touche Tohmatsu Limited ("DTTL"). Each Deloitte member firm is a separate legal entity and a member of DTTL. DTTL does not provide services to clients. Please see [www.deloitte.com/about](http://www.deloitte.com/about) to learn more.

v.E.1

---

**From:** Roe, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=536D87B3D3E74273A6D2DB52FA8C170B-LAURA.ROE]  
**Sent:** 7/31/2020 5:48:17 PM  
**To:** Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**Subject:** Aetion update  
**Attachments:** Aetion-FDA inpatient treatment-agnostic protocol for FDA review 07232020.docx; Aetion-FDA updated corticosteroid research approach 072320.pdf; Aetion-FDA updated presentation shared 072920.pdf; Aetion-FDA Updated RQ001 HCQ outpatient results 07232020.xlsx; Aetion-FDA ventilation definitions for FDA review 072320.docx

Dear all,

As discussed during our CMAG call yesterday, we have made steady progress in our research collaboration with Aetion. In the spirit of collaboration and rapid-cycle iteration, we would like to share several documents and questions that are top of mind in this collaborative effort. Outlined below, are some specifics around each of the attachments and questions that are surfacing in this discussion.

In advance of our Tuesday CMAG, please take a few minutes to take a look at these attachments and various points below. We aim to get input and thoughts on where we are with the next set of critical questions, answer the questions noted, and incorporate your feedback.

Thank you,

**(b)(5)**

**(b)(5)**

---

**From:** McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]  
**Sent:** 2/4/2020 1:37:07 PM  
**To:** Elwood, Will [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]  
**CC:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]  
**Subject:** Flagging as an FYI ONLY - please see before 1:50 pm today - planned FDA internal comms re: novel coronavirus - nCOV  
**Attachments:** Dear Colleagues.docx

Hi all – flagging the attached internal FDA email for awareness only – this is not yet public but, we hope to send to FDA employees later today. We have already shared with ASPR, NIH, CDC, and HHS OGA for awareness. Please let me know if I should share with others. Also, while this is just a courtesy flag, please do let us know if you do have any comments or questions by 1:50 today. Thank you!

**Megan McSeveney**

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514

(b)(5)

Megan.McSeveney@fda.hhs.gov



---

**From:** McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]  
**Sent:** 2/4/2020 4:20:53 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]  
**Subject:** Issuing shortly - FDA PR on EUA for CDC diagnostic to detect coronavirus  
**Attachments:** cov diagnostic eua\_PR-FDAcleared-2.4.20 (LM proof).docxmetaprnewswire.docx

Hi – the attached PR - FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic. Will issue shortly. Please do not share until this posts on our website. Thank you!



---

**From:** Alexander, Nicholas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08E1FD211C4A4C96BE426218BD0711E9-NICHOLAS.AL]  
**Sent:** 2/4/2020 5:51:29 PM  
**To:** Elwood, Will [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]  
**Subject:** FW: FDA approves sending Wuhan coronavirus test to states

FYSA

-- Nick

**Nick Alexander, J.D.**  
*Senior Advisor to the Deputy Commissioner*  
**Office of Policy, Legislation, and International Affairs**  
**Office of the Commissioner**  
**U.S. Food and Drug Administration**  
Direct: 301-796-8893 Mobile: (b)(6)  
nicholas.alexander@fda.hhs.gov



---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>  
**Sent:** Tuesday, February 4, 2020 5:39 PM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** FDA approves sending Wuhan coronavirus test to states

### **FDA approves sending Wuhan coronavirus test to states**

By David Lim

02/04/2020 05:38 PM EST

The FDA today granted emergency authorization for the CDC to distribute a diagnostic test for the Wuhan coronavirus to public health laboratories around the country.

The move allows states and localities to test patients, eliminating the need to confirm cases by sending samples to the CDC's headquarters in Atlanta. HHS Secretary Alex Azar today set the stage for authorization of the test by declaring that circumstances exist that justify its use.

"The ability to distribute this diagnostic test to qualified labs is a critical step forward in protecting the public health," FDA Commissioner Stephen Hahn said in a statement.

The FDA warned that negative test results do not necessarily rule out infection, saying other factors such as patient history and clinical observations should be taken into account.

There are currently 11 confirmed cases of coronavirus in the United States and public health officials have warned more cases are likely.

There is no commercially available diagnostic test for the Wuhan coronavirus that's approved by the FDA. The agency granted emergency authorizations after CDC developed tests in response to the outbreak of Ebola in West Africa from 2014 to 2016 and the Zika virus epidemic in North and South America in 2015 and 2016.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/02/fda-approves-sending-wuhan-coronavirus-test-to-states-3976321>



**You received this POLITICO Pro content because your customized settings include: Public Health. To change your alert settings, please go to <https://subscriber.politicopro.com/settings>.**

---



This email alert has been sent for the exclusive use of POLITICO Pro subscriber, [nicholas.alexander@fda.hhs.gov](mailto:nicholas.alexander@fda.hhs.gov). Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to [politicopro.com](http://politicopro.com).

---

This email was sent to [nicholas.alexander@fda.hhs.gov](mailto:nicholas.alexander@fda.hhs.gov) by:

POLITICO, LLC

1000 Wilson Blvd.

Arlington, VA 22209

USA .

---

**Sent:** 2/11/2020 9:23:40 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** RE: Request for Updates on Commissioner Sig Assignments Due 11:00 a.m., 2/11

Sure. Sorry if that was harsh, I'm annoyed at people this week.

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, February 11, 2020 9:21 AM  
**To:** Elwood, Will <William.Elwood@fda.hhs.gov>  
**Subject:** RE: Request for Updates on Commissioner Sig Assignments Due 11:00 a.m., 2/11

Thanks!

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** Elwood, Will <William.Elwood@fda.hhs.gov>  
**Sent:** Tuesday, February 11, 2020 9:16 AM  
**To:** Tropea, Josephine T. <Josephine.Tropea@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: Request for Updates on Commissioner Sig Assignments Due 11:00 a.m., 2/11

Hi Jo,

**(b)(6)**

but there's not much of an update on these. OPLIA is still reviewing (they've only had it for a week and coronavirus is consuming much of their time), and we don't have an estimate for you on timing but will follow-up with the front office. They understand the importance of these but there are competing priorities that they're juggling in a rapidly-evolving situation.

As far as the highlighted, the response to Gov. Parson will not clear until all the related letters clear because they're based on similar language. Separately, the Sen. Pennacchio letter continues to be **on hold** and will not move until a policy determination is made, as noted below, at the HHS level. This needs to be removed from our overdue list for now because it is on hold per the Department.

One thing I want to mention: It would be helpful if we received these update requests at least 24 hours before the information is needed. We can sometimes rely on them to help move things along, but when they arrive the same day the information is needed, we're unable to do that. If we receive these on Monday morning, that would be extremely helpful for us.

Thanks,  
Will

---

**From:** Tropea, Josephine T. <Josephine.Tropea@fda.hhs.gov>  
**Sent:** Tuesday, February 11, 2020 7:22 AM

**To:** Elwood, Will <William.Elwood@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** Request for Updates on Commissioner Sig Assignments Due 11:00 a.m., 2/11

Hi Will and Chris,

Please let me know if there are updates on the status of the letters below and if possible, include a date that OES should expect to get the draft response. Please provide an update by 11:00 a.m., today, 2/11.

The two items highlight below are past due for HHS's review and the Parson response needs to be sent this week .

Thanks again,  
Jo

### **Overdue Commissioner Signature Assignments**

1. 2019-4648 - The letter is from Mayor Fischer of Louisville, Kentucky to Commissioner Hahn expressing concerns about FDA's response to date to the vaping epidemic and reducing use of e-cigarettes among our youth and urges the Commissioner to take swift action to restrict the sale of all flavored e-cigarette products. **Due:1/6/12. Assigned to IAS -Letter with /OPLIA/Anna Abram for review.**
2. 2019-4497 - The letter is from Monica Bharel, Commissioner of the Commonwealth of Massachusetts Department of Public Health to Admiral Giroir submitting recommendations for FDA's consideration to regulate vaping products. **Due: 12/16/19. Assigned to IAS. - Letter with /OPLIA/Anna Abram for review.**
3. 2019-4083 - The letter is from Mike DeWine, Governor of Ohio to Dr. Sharpless expressing his concerns regarding flavored e-cigarette products and the epidemic of youth vaping. Urges FDA to start enforcement actions against companies marketing these products. **Due:11/6/19 Assigned to IAS. Letter with /OPLIA/Anna Abram for review.**
4. 2019-4077 - **(Department R/C)** The letter is from Michael Parson, Governor, state of Missouri to Secretary Azar expressing concerns regarding the use of electronic vapor products by our youth and urges the Department to continue to work on keeping these products out of the hands of our youth. (cross reference 2019-4078 identical letter to Acting Commissioner) **Due:10/29/19 Assigned to IAS. Letter with /OPLIA/Anna Abram for review.**
5. 2019-4078 - **(Note: Secretary Azar rec'd same letter 2019-4077 for Department R/C.)** The letter is from Michael Parson, Governor, state of Missouri to Secretary Azar expressing concerns regarding the use of electronic vapor products by our youth and urges the Department to continue to work on keeping these products out of the hands of our youth. (note: will send one response) **Due:10/29/19. Assigned to IAS. Letter with /OPLIA/Anna Abram for review.**
6. 2019-3934 - The letter is from Stephen Sweeney, Senate President, State of New Jersey to Dr. Sharpless expressing concerns regarding the vapor epidemic and in follow-up to the recent hearing, submits recommendations for FDA to consider. **Due: 10/24/19. Assigned to IAS. Letter with /OPLIA/Anna Abram for review.**
7. 2019-3899 - **(Department R/C.)** The letter is from Senator Pennacchio of the State of New Jersey to President Trump requesting an exemption to Cigars for Warriors an organization that sends cigars to troops serving in combat zones overseas. **Due: 10/15/19. Assigned to IAS. Per HHS, this letter on hold given sensitivities around the issue.**



---

**From:** McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]  
**Sent:** 2/14/2020 3:47:01 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]  
**Subject:** FYI -issuing shortly -FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad  
**Attachments:** ASPACLEAREDCOVIDstatementforTemplate021420prnewswire.docx

Hi – the attached statement - FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad - will issue shortly. Please do not share until this posts on our website. Thank you!

**Megan McSeveney**

Press Officer

Office of Media Affairs  
Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cell: (b)(6)

Megan.McSeveney@fda.hhs.gov



---

**From:** Wiley, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DB729BC60C0140FD968242E8C817D38C-WILEYE]  
**Sent:** 2/14/2020 4:22:35 PM  
**To:** O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILL]; Rovin, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ab536b0812946e782a5635c5e3e37da-Lisa.Rovin]; Lorraine, Catherine C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90e35615643448749b1dcd99f3fec869-CLORRAIN]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Wiley, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db729bc60c0140fd968242e8c817d38c-WILEYE]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bd04f42f0afb9dd6abf39793a-Daniel.Hatt]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]  
**CC:** Tropea, Josephine T. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7448bd63bffe4ea2b20b87816b18faaa-jts]; Rollins, Michele A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77427a3040f94ad2a36144eb960b7b4f-Michele.Rol]; Sobel, Isabel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4939ca1a32e467986d4d6d143c8c8ba6-ISobel]; Jackson, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbeac5d29ba247128b43177b06d5d847-VJackson]; Flamm, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72d91495273741e0ae2b7c6cf01b9e3c-EFLAMM]; Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Cardin, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c1d42251310b4a328f2a677de8b101b1-Megan.Cardi]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Shapley, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd55e42834c47d583e1fc7a756a0a06-SSHAPLEY]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Anderson, Erika

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Dooren, Jennifer  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Lenihan, Keagan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Copeland, Jakea  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Cristinzio, Dayle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Rabin, Tara G.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Stark, Angela  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Hinton, Denise  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Nguyen, Michael A.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Davies, Kathleen  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Helms Williams, Emily  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zembower, Jenna  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Elwood, Will  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tarver, Darian B.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Dupont, Jarilyn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Lyndsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Meyer, Raymond  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09b2e97a15624941aef7b5b4ae5c12de-MEYERR]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hoffman, Allison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]

**Subject:** Internal Strategic Planning (ISP) Meeting \*Materials added  
**Attachments:** ISP Agenda 2-18-20 Final.docx; FDA Communications Forecast\_2.28.20.docx; WAR FINAL 2-13-20.pdf  
**Location:** WO Building 1, Conference Room 2101 or Call In: 877-465-7975/Access Code: (b)(6)

**Start:** 2/18/2020 9:30:00 AM  
**End:** 2/18/2020 10:15:00 AM  
**Show Time As:** Tentative

---

**Recurrence:** Weekly  
every Tuesday from 9:30 AM to 10:15 AM

**Required Attendees:** O'Neill, Jeff; Rovin, Lisa; Lorraine, Catherine C; Cohen, Kenneth; Rebello, Heidi; Tyler, James; Wiley, Elizabeth; Alexander, Nicholas; McBride, Maren; Beardsley, Sara; Hattis, Daniel; Klimczak, Katherine

**Optional Attendees:** Tropea, Josephine T.; Rollins, Michele A; Sobel, Isabel; Jackson, Valerie; Flamm, Eric; Helmanis, Lisa M; Tantillo, Andrew; Schiller, Lowell; McWilliams, Carly; Cardin, Megan; Peddicord, Sarah; Shapley, Stephanie; Roth, Lauren; Sheehy, Janice; Lutter, Randall; Anderson, Erika; Dooren, Jennifer; Lenihan, Keagan; Copeland, Jakea; Cristinzio, Dayle; Rabin, Tara G.; Stark, Angela; Hinton, Denise; Nguyen, Michael A.; Davies, Kathleen; Helms Williams, Emily; Flahive, James; Tobias, Lindsay; Zembower, Jenna; Elwood, Will; Franklin, Joseph; Rom, Colin; Tarver, Darian B.; Dupont, Jarilyn; Felberbaum, Michael; Meyer, Lyndsay; Meyer, Raymond; Walsh, Sandy; Hoffman, Allison

\*Materials added for 2/18/2020:



ISP Agenda  
2-18-20 Final.docx



FDA  
Communications...



WAR FINAL  
2-13-20.pdf

**Internal Strategic Planning (ISP) Meeting** is held weekly on Tuesday's at 9:30 am.

**Location:** White Oak, Building 1, *Conference Room 2101*

**Directions using a WebEx number:**

1. Toll Free: 1-877-465-7975 or 1-210-795-0506 US Toll
2. Enter Access Code  press # (No pin required for attendees)

Please do not forward this invite.

If you have questions, please contact Elizabeth (Betsy) Wiley, 301-796-3479.



---

**From:** Elwood, Will [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BE0131FF86E94523A3574EB66E9FA68-WILLIAM.ELW]  
**Sent:** 2/18/2020 5:20:07 PM  
**To:** Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]  
**Subject:** RE: Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

I responded to this for IGA.

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 5:15 PM  
**To:** Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>  
**Cc:** Finnen, April <April.Finnen@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

Sandy – I am looping in my colleagues from the Office of Intergovernmental affairs, who handle all things state and local.

---

**From:** Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 5:05 PM  
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Cc:** Finnen, April <April.Finnen@fda.hhs.gov>  
**Subject:** Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief  
**Importance:** High

Hi Andrew, please see below – is it correct to add in something

(b)(5)

(b)(5) if so please add where appropriate.

Sandy Walsh  
*Acting Director*  
Office of Editorial and Creative Services  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 301-796-4669  
Sandy.Walsh@fda.hhs.gov



---

**From:** Mettler, Erik <Erik.Mettler@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 3:51 PM  
**To:** Finnen, April <April.Finnen@fda.hhs.gov>  
**Subject:** RE: JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

April, are we working with the State and local health departments? Id so you might consider working that into the below.

---

**From:** Finnen, April <April.Finnen@fda.hhs.gov>

**Sent:** Tuesday, February 18, 2020 3:43 PM

**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

**Subject:** JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

JIC – FYI, text below for an FDA In Brief readout on Commissioner Hahn’s visit to the HHS SOC last Friday. Target date to issue is Wed. Feb. 18.

Please make any suggested edits to the SP version only before 5:00 p.m. today. If you do not have comments, no need to respond. Questions to Sandy Walsh.

Draft below FYI only.

**(b)(5)**

**(b)(5)**

IMG JIC Lead

2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)

U.S. Food and Drug Administration

Desk: 240-402-0470

EOC: (b)(6) (hours at EOC: M, Tu, Th 9:00 a.m. – 11:30 a.m., 1:00 – 3:00 p.m.)

Cell: (b)(6)

Email: [april.finnen@fda.hhs.gov](mailto:april.finnen@fda.hhs.gov)

JIC (Joint Information Center) email: [2019-nCoVFDAIMGJIC@fda.hhs.gov](mailto:2019-nCoVFDAIMGJIC@fda.hhs.gov)



---

**From:** Elwood, Will [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BE0131FF86E94523A3574EB66E9FA68-WILLIAM.ELW]  
**Sent:** 2/18/2020 7:05:51 PM  
**To:** Norris, Gary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc19fae0c7d44332a71e1ff7aa2cefbc-Gary.Norris]  
**Subject:** RE: Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

Great – thanks Gary.

---

**From:** Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 7:04 PM  
**To:** Elwood, Will <William.Elwood@fda.hhs.gov>  
**Subject:** RE: Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

Thanks, Will – got it!  
Best,  
Gary

**Gary Norris**, MS, MPA, ASQ CMQ/OE, MT(ASCP)SBB  
Federal-State Health Communications and Relations Program Manager  
Division of Communications  
Office of Communications and Project Management

**U.S. Food and Drug Administration**

Office of Regulatory Affairs  
5630 Fishers Lane, RM 1089  
Rockville, Maryland  
Office: (301) 796-5781 | BlackBerry: (b)(6) | Fax: (301) 827-4106  
Email: Gary.Norris@fda.hhs.gov



---

**From:** Elwood, Will <William.Elwood@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 5:20 PM  
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>  
**Cc:** Finnen, April <April.Finnen@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Subject:** RE: Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

Thanks Andy. Removing Nick who's on detail to OPLIA.

I'm adding my colleague, Mr. Norris, in ORA who'd be aware of any work w/ state/local health depts. on this issue.

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 5:15 PM

**To:** Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>  
**Cc:** Finnen, April <April.Finnen@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

Sandy – I am looping in my colleagues from the Office of Intergovernmental affairs, who handle all things state and local.

---

**From:** Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 5:05 PM  
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Cc:** Finnen, April <April.Finnen@fda.hhs.gov>  
**Subject:** Andrew - JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief  
**Importance:** High

Hi Andrew, please see below – is it correct to add in something (b)(5) (b)(5) if so please add where appropriate.

Sandy Walsh  
*Acting Director*  
Office of Editorial and Creative Services  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 301-796-4669  
Sandy.Walsh@fda.hhs.gov



---

**From:** Mettler, Erik <Erik.Mettler@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 3:51 PM  
**To:** Finnen, April <April.Finnen@fda.hhs.gov>  
**Subject:** RE: JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

(b)(5)

---

**From:** Finnen, April <April.Finnen@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 3:43 PM  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Subject:** JIC FYI review - comment by 5:00 p.m. today 2/18 - HHS SOC readout In Brief

JIC – FYI, text below for an FDA In Brief readout on Commissioner Hahn’s visit to the HHS SOC last Friday. Target date to issue is Wed. Feb. 18.

Please make any suggested edits to the SP version only before 5:00 p.m. today. If you do not have comments, no need to respond. Questions to Sandy Walsh.

Draft below FYI only.

**(b)(5)**

**(b)(5)**

###

**April Finnen**

IMG JIC Lead

**2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)**

**U.S. Food and Drug Administration**

Desk: 240-402-0470

EOC: 301-796-8281 (hours at EOC: M, Tu, Th 9:00 a.m. – 11:30 a.m., 1:00 – 3:00 p.m.)

Cell: (b)(6)

Email: [april.finnen@fda.hhs.gov](mailto:april.finnen@fda.hhs.gov)

JIC (Joint Information Center) email: [2019-nCoVFDAIMGJIC@fda.hhs.gov](mailto:2019-nCoVFDAIMGJIC@fda.hhs.gov)





---

**From:** Cooper, Mildred [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA838567FF8147FFB5933A8A698133B0-MILDRED.COO]  
**Sent:** 2/21/2020 3:55:48 PM  
**To:** OC-Executive Secretariat-Policy Analysts [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f9e7ff68a04df59c53698f65bac2f6-OC-Executiv]; OEA External Communications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dc23bbf65b0459eb8661d53c2fcd341-OEA Externa]  
**Subject:** FDA Communications Forecast (Mon., Feb. 24 - Fri., Mar. 6)  
**Attachments:** FDA Communications Forecast\_3.6.20.docx

Please find attached the FDA Communications Forecast for the next two weeks (Mon., Feb. 24 - Fri., Mar. 6).

As a reminder, it contains commercial confidential information.

Best,

Mildred

---

**From:** Meyer, Raymond [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=09B2E97A15624941AEF7B5B4AE5C12DE-MEYERR]

**Sent:** 2/24/2020 4:15:49 PM

**To:** O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILL]; Rovin, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ab536b0812946e782a5635c5e3e37da-Lisa.Rovin]; Lorraine, Catherine C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90e35615643448749b1dcd99f3fec869-CLORRAIN]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Wiley, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db729bc60c0140fd968242e8c817d38c-WILEYE]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bd04f42f0afb9dd6abf39793a-Daniel.Hatt]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]

**CC:** Tropea, Josephine T. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7448bd63bffe4ea2b20b87816b18faaa-jts]; Rollins, Michele A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77427a3040f9ad2a36144eb960b7b4f-Michele.Rol]; Sobel, Isabel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4939ca1a32e467986d4d6d143c8cba6-ISobel]; Jackson, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbeac5d29ba247128b43177b06d5d847-VJackson]; Flamm, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72d91495273741e0ae2b7c6cf01b9e3c-EFLAMM]; Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Cardin, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c1d42251310b4a328f2a677de8b101b1-Megan.Cardi]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Shapley, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd55e42834c47d583e1fc7a756a0a06-SSHAPLEY]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Anderson, Erika

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Dooren, Jennifer  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Lenihan, Keagan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Copeland, Jakea  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Cristinzio, Dayle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Rabin, Tara G.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Stark, Angela  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Hinton, Denise  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Nguyen, Michael A.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Davies, Kathleen  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Helms Williams, Emily  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zembower, Jenna  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Elwood, Will  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tarver, Darian B.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Dupont, Jarilyn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Lyndsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Meyer, Raymond  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09b2e97a15624941aef7b5b4ae5c12de-MEYERR]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hoffman, Allison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]

**Subject:** Internal Strategic Planning (ISP) Meeting  
**Attachments:** ISP Agenda 2-25-20 Final.docx; WAR FINAL 2-20-20.pdf; FDA Communications Forecast\_3.6.20.docx  
**Location:** WO Building 1, Conference Room 2101 or Call In: 877-465-7975/Access Code (b)(6)  
**Start:** 2/25/2020 9:30:00 AM  
**End:** 2/25/2020 10:15:00 AM  
**Show Time As:** Tentative

---

**Recurrence:** Weekly  
every Tuesday from 9:30 AM to 10:15 AM

**Required Attendees:** O'Neill, Jeff; Rovin, Lisa; Lorraine, Catherine C; Cohen, Kenneth; Rebello, Heidi; Tyler, James; Wiley, Elizabeth; Alexander, Nicholas; McBride, Maren; Beardsley, Sara; Hattis, Daniel; Klimczak, Katherine

**Optional Attendees:** Tropea, Josephine T.; Rollins, Michele A; Sobel, Isabel; Jackson, Valerie; Flamm, Eric; Helmanis, Lisa M; Tantillo, Andrew; Schiller, Lowell; McWilliams, Carly; Cardin, Megan; Peddicord, Sarah; Shapley, Stephanie; Roth, Lauren; Sheehy, Janice; Lutter, Randall; Anderson, Erika; Dooren, Jennifer; Lenihan, Keagan; Copeland, Jakea; Cristinzio, Dayle; Rabin, Tara G.; Stark, Angela; Hinton, Denise; Nguyen, Michael A.; Davies, Kathleen; Helms Williams, Emily; Flahive, James; Tobias, Lindsay; Zembower, Jenna; Elwood, Will; Franklin, Joseph; Rom, Colin; Tarver, Darian B.; Dupont, Jarilyn; Felberbaum, Michael; Meyer, Lyndsay; Meyer, Raymond; Walsh, Sandy; Hoffman, Allison

02/24/2020: Materials added



ISP Agenda  
2-25-20 Final.docx



WAR FINAL  
2-20-20.pdf



FDA  
Communications...

**Internal Strategic Planning (ISP) Meeting** is held weekly on Tuesday's at 9:30 am.

**Location:** White Oak, Building 1, *Conference Room 2101*.

**Directions using a WebEx number:**

1. Toll Free: 1-877-465-7975 or 1-210-795-0506 US Toll
2. Enter Access Code **(b)(6)** press # (No pin required for attendees)

Please do not forward this invite.

If you have questions, please contact Elizabeth (Betsy) Wiley, 301-796-3479.

---

**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
**Sent:** 2/27/2020 2:19:29 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]  
**Subject:** FYI, preparing to issue, coronavirus update and supply chain  
**Attachments:** Supply chain draft statement\_2.27.20\_final to issue\_215pm.docx

Hi!

OMA will shortly issue the attached statement on a coronavirus update and supply chain. Please do not share until it is on the FDA website.

Thanks,

**Stephanie Caccomo**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.344.1956  
Cell: (b)(6)  
stephanie.caccomo@fda.hhs.gov



---

**From:** Saghafi, Michelle [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C64D4CC782A94188AE15E0549DFFEFCA-MICHELLE.SA]  
**Sent:** 2/28/2020 3:55:39 PM  
**To:** OC-Executive Secretariat-Policy Analysts [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f9e7ff68a04df59c53698f65bac2f6-OC-Executiv]; OEA External Communications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dc23bbf65b0459eb8661d53c2fcd341-OEA Externa]  
**Subject:** FDA Communications Forecast (Mon., Mar. 2 - Fri., Mar. 13)  
**Attachments:** FDA Communications Forecast\_3.13.20.docx

Please find attached the FDA Communications Forecast for the next two weeks (Mon., Mar. 2 - Fri., Mar. 13).

As a reminder, it contains commercial confidential information.

Best,

Michelle

**Michelle A. Saghafi, MBA**

*Public Affairs Specialist*

Office of Editorial and Creative Services

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-8628 / Cell: (b)(6)

michelle.saghafi@fda.hhs.gov



---

**From:** Wiley, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DB729BC60C0140FD968242E8C817D38C-WILEYE]  
**Sent:** 3/2/2020 5:39:25 PM  
**To:** O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]; Rovin, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ab536b0812946e782a5635c5e3e37da-Lisa.Rovin]; Lorraine, Catherine C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90e35615643448749b1dcd99f3fec869-CLORRAIN]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Wiley, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db729bc60c0140fd968242e8c817d38c-WILEYE]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bd04f42f0afb9dd6abf39793a-Daniel.Hatt]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]  
**CC:** Tropea, Josephine T. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7448bd63bffe4ea2b20b87816b18faaa-jts]; Rollins, Michele A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77427a3040f94ad2a36144eb960b7b4f-Michele.Rol]; Sobel, Isabel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4939ca1a32e467986d4d6d143c8cba6-ISobel]; Jackson, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbeac5d29ba247128b43177b06d5d847-VJackson]; Flamm, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72d91495273741e0ae2b7c6cf01b9e3c-EFLAMM]; Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Cardin, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c1d42251310b4a328f2a677de8b101b1-Megan.Cardi]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Shapley, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd55e42834c47d583e1fc7a756a0a06-SSHAPLEY]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Anderson, Erika

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Dooren, Jennifer  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Lenihan, Keagan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Copeland, Jakea  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Cristinzio, Dayle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Rabin, Tara G.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Stark, Angela  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Hinton, Denise  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Nguyen, Michael A.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Davies, Kathleen  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Helms Williams, Emily  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zembower, Jenna  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Elwood, Will  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tarver, Darian B.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Dupont, Jarilyn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Lyndsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Meyer, Raymond  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09b2e97a15624941aef7b5b4ae5c12de-MEYERR]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hoffman, Allison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]

**Subject:** Internal Strategic Planning (ISP) Meeting \*Materials added  
**Attachments:** ISP Agenda 3-3-20 Final.docx; FDA Communications Forecast\_3.13.20.docx; WAR.FINAL.2-27-20.pdf  
**Location:** WO Building 1, Conference Room 2101 or Call In: 877-465-7975/Access Code: (b)(6)

**Start:** 3/3/2020 9:30:00 AM  
**End:** 3/3/2020 10:15:00 AM  
**Show Time As:** Tentative



---

**Recurrence:** Weekly  
every Tuesday from 9:30 AM to 10:15 AM

**Required Attendees:** O'Neill, Jeff; Rovin, Lisa; Lorraine, Catherine C; Cohen, Kenneth; Rebello, Heidi; Tyler, James; Wiley, Elizabeth; Alexander, Nicholas; McBride, Maren; Beardsley, Sara; Hattis, Daniel; Klimczak, Katherine

**Optional Attendees:** Tropea, Josephine T.; Rollins, Michele A; Sobel, Isabel; Jackson, Valerie; Flamm, Eric; Helmanis, Lisa M; Tantillo, Andrew; Schiller, Lowell; McWilliams, Carly; Cardin, Megan; Peddicord, Sarah; Shapley, Stephanie; Roth, Lauren; Sheehy, Janice; Lutter, Randall; Anderson, Erika; Dooren, Jennifer; Lenihan, Keagan; Copeland, Jakea; Cristinzio, Dayle; Rabin, Tara G.; Stark, Angela; Hinton, Denise; Nguyen, Michael A.; Davies, Kathleen; Helms Williams, Emily; Flahive, James; Tobias, Lindsay; Zembower, Jenna; Elwood, Will; Franklin, Joseph; Rom, Colin; Tarver, Darian B.; Dupont, Jarilyn; Felberbaum, Michael; Meyer, Lyndsay; Meyer, Raymond; Walsh, Sandy; Hoffman, Allison

**\*Materials for March 3, 2020:**



ISP Agenda 3-3-20  
Final.docx



FDA  
Communications...



WAR FINAL  
2-27-20.pdf

**Internal Strategic Planning (ISP) Meeting** is held weekly on Tuesday's at 9:30 am.

**Location:** White Oak, Building 1, **Conference Room 2101**

**Directions using a WebEx number:**

1. Toll Free: 1-877-465-7975 or 1-210-795-0506 US Toll
2. Enter Access Code (b)(6) press # (No pin required for attendees)

Please do not forward this invite.

If you have questions, please contact Elizabeth (Betsy) Wiley, 301-796-3479.

---

**From:** Varnado, Martina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AD1D1BC50F7941718B0FEEB194CBAFF1-MARTINA.VAR]  
**Sent:** 3/2/2020 5:39:29 PM  
**To:** Varnado, Martina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad1d1bc50f7941718b0feeb194cbaff1-Martina.Var]; O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]; Rovin, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ab536b0812946e782a5635c5e3e37da-Lisa.Rovin]; Lorraine, Catherine C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90e35615643448749b1dcd99f3fec869-CLORRAIN]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Wiley, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db729bc60c0140fd968242e8c817d38c-WILEYE]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bd04f42f0afb9dd6abf39793a-Daniel.Hatt]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]  
**CC:** Tropea, Josephine T. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7448bd63bffe4ea2b20b87816b18faaa-jts]; Rollins, Michele A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77427a3040f94ad2a36144eb960b7b4f-Michele.Rol]; Sobel, Isabel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4939ca1a32e467986d4d6d143c8cba6-ISobel]; Jackson, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbeac5d29ba247128b43177b06d5d847-VJackson]; Flamm, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72d91495273741e0ae2b7c6cf01b9e3c-EFLAMM]; Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Cardin, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c1d42251310b4a328f2a677de8b101b1-Megan.Cardi]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Shapley, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd55e42834c47d583e1fc7a756a0a06-SSHAPLEY]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lutter, Randall

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Anderson, Erika  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Dooren, Jennifer  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Lenihan, Keagan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Copeland, Jakea  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Cristinzio, Dayle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Rabin, Tara G.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Stark, Angela  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Hinton, Denise  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Nguyen, Michael A.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Davies, Kathleen  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Helms Williams, Emily  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zembower, Jenna  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Elwood, Will  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tarver, Darian B.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Dupont, Jarilyn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Lyndsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Meyer, Raymond  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09b2e97a15624941aef7b5b4ae5c12de-MEYERR]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hoffman, Allison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]

**Subject:** Internal Strategic Planning (ISP) Meeting \*Materials added

**Attachments:** ISP Agenda 3-3-20 Final.docx; FDA Communications Forecast\_3.13.20.docx; WAR FINAL 2-27-20.pdf

**Location:** WO Building 1, Conference Room 2101 or Call In: 877-465-7975/Access Code: (b)(6)

**Start:** 3/3/2020 9:30:00 AM

**End:** 3/3/2020 10:15:00 AM

**Show Time As:** Tentative

---

**Recurrence:** Weekly  
every Tuesday from 9:30 AM to 10:15 AM

**Required Attendees:** O'Neill, Jeff; Rovin, Lisa; Lorraine, Catherine C; Cohen, Kenneth; Rebello, Heidi; Tyler, James; Wiley, Elizabeth; Alexander, Nicholas; McBride, Maren; Beardsley, Sara; Hattis, Daniel; Klimczak, Katherine

**Optional Attendees:** Tropea, Josephine T.; Rollins, Michele A; Sobel, Isabel; Jackson, Valerie; Flamm, Eric; Helmanis, Lisa M; Tantillo, Andrew; Schiller, Lowell; McWilliams, Carly; Cardin, Megan; Peddicord, Sarah; Shapley, Stephanie; Roth, Lauren; Sheehy, Janice; Lutter, Randall; Anderson, Erika; Dooren, Jennifer; Lenihan, Keagan; Copeland, Jakea; Cristinzio, Dayle; Rabin, Tara G.; Stark, Angela; Hinton, Denise; Nguyen, Michael A.; Davies, Kathleen; Helms Williams, Emily; Flahive, James; Tobias, Lindsay; Zembower, Jenna; Elwood, Will; Franklin, Joseph; Rom, Colin; Tarver, Darian B.; Dupont, Jarilyn; Felberbaum, Michael; Meyer, Lyndsay; Meyer, Raymond; Walsh, Sandy; Hoffman, Allison

\*Materials for March 3, 2020:



ISP Agenda 3-3-20  
Final.docx



FDA  
Communications...



WAR FINAL  
2-27-20.pdf

**Internal Strategic Planning (ISP) Meeting** is held weekly on Tuesday's at 9:30 am.

**Location:** White Oak, Building 1, **Conference Room 2101**

**Directions using a WebEx number:**

- 1. Toll Free:** 1-877-465-7975 or 1-210-795-0506 US Toll
- 2. Enter Access Code**  **press #** (No pin required for attendees)

**Please do not forward this invite.**

If you have questions, please contact Elizabeth (Betsy) Wiley, 301-796-3479.

---

**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
**Sent:** 3/2/2020 7:09:27 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]  
**Subject:** preparing to issue: press release on respirator EUA  
**Attachments:** draft\_PR\_N95s\_3.2.20\_535.docx

Hi—  
OMA will shortly issue the attached press release on the FDA/CDC EUA on respirators, including N95s. Please do not distribute until it is publicly on the FDA webpage.

**Stephanie Caccomo**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301-348-1956  
Cell: (b)(6)  
stephanie.caccomo@fda.hhs.gov



**From:** NATIONAL JIC (b)(6)  
**Sent:** 3/3/2020 2:28:15 PM  
**Location:** Hogan.Gidley (b)(6); Ditto, Jessica E; Adam.R.Kenned (b)(6); Judson.P.Deere (b)(6);  
Tori.Q.Symonds (b)(6); Hoelscher, Douglas L.; Nicholas.D.Pottebaum (b)(6);  
William.F.Crozet (b)(6); Olivia.P.Imhoff (b)(6)  
**Start:** 3/4/2020 12:30:00 PM  
**End:** 3/4/2020 1:00:00 PM  
**Show Time As:** Tentative

**Recurrence:** (none)

ESF-8 and other interagency communication colleagues,

Please join the Department of HHS and NSC Press Office for a Sunday National Incident Communication Conference Line Call (NICCL) to discuss the coronavirus.

We plan to conduct the call on 3/4/2020 at 1230 (eastern) for approximately 30 minutes. Please keep your phone on mute throughout this NICCL call.

1-800-320-4330 code (b)(6)

Strict 30 minute agenda

- Departments / Agency dialed in NLT 5:15pm (eastern)
- Selected roll call prompted by HHS
- Opening comments by (b)(6) (NCS Press Office)
- Public Health updates
- Other D/A communication input
- Questions and answer period (announce your agency and name please)
- Final comments by NSC and HHS

If you need to add someone to this NICCL coordination please contact this nationaljic@dhs.gov email or (b)(6)

If you need to contact the CDC JIC use eocjiclead2@cdc.gov and/or eocjictriage2@cdc.gov

All currently available information and resources are available at <https://www.cdc.gov/coronavirus> (or [www.cdc.gov/ncov](http://www.cdc.gov/ncov))

**Key contacts:**

HHS Deputy Assistant Secretary for Public Affairs for Public Health, Bill Hall, 202-690-6344 or 202-823-2008; bill.hall@hhs.gov  
NSC Press Office, (b)(6)  
Dept of State, taskforce4mailbox@state.gov

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/9/2020 9:09:37 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Elwood, Will [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]  
**Subject:** RE: COVID Response

Good question. Lets discuss at team meeting.

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Monday, March 09, 2020 9:01 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>  
**Subject:** RE: COVID Response

Thanks, Karen. Can you let us know who in the Agency is the point person for COVID in case we get inquiries from State/local stakeholders (which we will, I am sure!). Thanks! Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 2:25 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: COVID Response

FYI only

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Thursday, March 05, 2020 1:59 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Response

For all manufacturer questions, we point them to the review office to address their technical questions. Please let them know that FDA is available to talk by phone or email to address any of their questions, and specifically about COVID related issues. Please see the information below which is also on [FDA.gov](https://www.fda.gov)

On February 29, 2020, the FDA issued an immediately in effect guidance, Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency. The template for these EUA submissions is available.

If you need additional information about completing the template or wish to consider use of an alternative specimen type, please contact the Division of Microbiology devices at (301) 348-1778 or email [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov).



---

**From:** Jenni.Wai@pharmacy.ohio.gov [Jenni.Wai@pharmacy.ohio.gov]  
**Sent:** 3/12/2020 10:06:29 AM  
**To:** Elwood, Will [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]  
**Subject:** COVID-19 and sterile compounding impact  
**Attachments:** COVID-19 Downstream Implications updated 20200304.pdf

Good morning Will,

I hope this message finds you well!

As you are aware of the COVID-19 and its downstream implications on healthcare, we are receiving requests regarding to guidance on conservation of garb use for sterile compounding. Most importantly, we have been asked if masks can be re-use to conserve as some institutions and compounding pharmacies are seeing an intermittent shortage on medical supplies.

The attached PDF was webinar from Critical Point, who provides training on sterile compounding and state inspector certification course. This was provided to us by the requestor.

<https://www.criticalpoint.info/>

Does FDA have any guidance on conservation or reuse of sterile compounding garb that you may provide?

This has escalated very quickly.

Thank you for your guidance!



**STATE OF  
OHIO**  
BOARD OF PHARMACY

**Jenni Wai, RPh., MBA.**

Chief Pharmacist

77 South High Street, 17<sup>th</sup> Floor, Columbus, Ohio 43215

T: (614) 466-4143 | F: (614) 752-4836

Jenni.Wai@pharmacy.ohio.gov

[www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)

*This e-mail may contain sensitive law enforcement and/or privileged information. If you are not the intended recipient (or have received this e-mail in error) please notify the sender and destroy this e-mail. Any unauthorized copying, disclosure or distribution of the material in this e-mail is strictly forbidden. This message and any response to it may constitute a public record and thus may be publicly available to anyone who requests it.*

---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/16/2020 8:09:35 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** FDA Issues Guidance for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency

Good morning -

FDA's Intergovernmental Affairs (IGA) team wanted to bring your attention that due to the Coronavirus Disease 2019 (COVID-19) pandemic, the Agency has received a number of queries concerning compounding of alcohol-based hand sanitizers. The FDA has issued guidance: [Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](#) to communicate its policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Best,

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)



---

**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
**Sent:** 3/16/2020 6:59:15 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** preparing to issue: diagnostic policy statement  
**Attachments:** Diagnostic guidance\_updated policy\_3.16.20\_7pm to issue.docx

Hi-  
This is issuing now. Thanks!

---

**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
**Sent:** 3/16/2020 8:35:45 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** Preparing to issue: FDA grants 2 EUAs  
**Attachments:** Hologic\_3.16.20\_816pm.docx

Hi! This is preparing to issue on the FDA website. The EUAs were granted this evening.

Thanks!

---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/17/2020 7:51:43 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** Coronavirus (COVID-19) Update: FDA Continues to Help Expedite Availability of Diagnostics

Good morning-

The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention to the following press releases on FDA's actions to continue to expedite availability of diagnostics for COVID-19.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Best,

Chris

## **Coronavirus (COVID-19) Update: FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics**

*The following is attributed to FDA Commissioner Stephen M. Hahn, M.D.*

Today, as part of our ongoing and aggressive commitment to address the coronavirus outbreak, the FDA updated a policy originally issued on Feb. 29 on diagnostic testing for coronavirus (COVID-19) in order to achieve more rapid testing capacity in the U.S. We believe the unprecedented policy set forth in today's updated guidance, which addresses laboratories and commercial manufacturers, will help address these urgent public health concerns by helping to expand the number and variety of diagnostic tests, as well as available testing capabilities in health care settings, and reference and commercial laboratories.

This action demonstrates the FDA's ability to pivot and adapt as the situation warrants in light of a public health emergency. We are taking steps to support diagnostic development considering the urgent need. We urge state authorities and commercial developers to take all necessary steps to ensure the availability of accurate tests. Inaccurate diagnoses during a pandemic can impair prevention efforts and delay appropriate treatment for sick patients.

Our guidance provides more specific details for the laboratory and commercial manufacturer communities, but I want to highlight three key elements of the update we are issuing today.

First, we are putting in place a policy for states to take responsibility for tests developed and used by laboratories in their states, similar to the action the FDA granted to the New York State Department of Health last week. States can set up a system in which they take responsibility for authorizing such tests and the laboratories will not engage with the FDA. As stated in the guidance, the system does not need to mirror that of New York. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of with the FDA. Nor will these laboratories pursue an Emergency Use Authorization (EUA) with the FDA.

Second, we are expanding who the policy outlined in the Feb. 29 guidance applies to. The policy was originally applicable only to laboratories that are certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments. Under the update published today, the agency does not intend to object to commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an EUA, under certain circumstances. The FDA is aware that numerous commercial manufacturers are developing tests for

coronavirus with the intention of submitting an EUA to the FDA. During this public health emergency, the FDA does not intend to object to the distribution and use of these tests for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. As noted in the guidance, the FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated by the manufacturer.

Finally, our updated policy provides recommendations for test developers who may wish to develop serological tests for use during this coronavirus outbreak. Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection. We recognize that serology tests are less complex than molecular tests and are solely used to identify antibodies, which limits their effectiveness for diagnosis; however, as stated in the updated guidance, the FDA does not intend to object to the distribution and use of serology tests to identify antibodies to SARS-CoV-2 where the test has been validated, notification is provided to the FDA, and warning statements are included with the tests, for example, noting the test has not been reviewed by the FDA and results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

#### *FDA Support of Diagnostics*

The FDA has engaged with more than 100 test developers since the end of January, providing templates and advice about the EUA process. More than 80 developers have sought our assistance with development and validation of tests they plan to bring through the EUA process. We've granted multiple diagnostic EUAs during this outbreak.

We are updating frequently asked questions for labs and test developers, providing information on alternative sources of reagents, extraction kits, swabs and more.

We've also set up a toll-free line, 1-888-INFO-FDA, to help labs with any questions they may have about the EUA process, our policies or getting supplies.

We know that people want to know the current numbers of tests in the field and how many patients are being tested. This number fluctuates daily as more and more test developers get their tests in the field and start testing patients. At this time, the FDA is focused on making sure tests are distributed and that test developers and labs have the materials they need to run the tests.

The FDA continues to maintain operations 24/7 and we are here to support laboratories and test developers as they distribute tests through the country during this time of urgent need.

Additional Resources:

- [Novel Coronavirus](#)

following press release on the issuance of two EUAs to Hologic and LabCorp. If you have any questions, please contact [Taylor Price](#) for further information regarding this announcement. Thank you.

## **Coronavirus (COVID-19) Update: FDA Issues Diagnostic Emergency Use Authorization to Hologic and LabCorp**

Today, the U.S. Food and Drug Administration took two additional significant diagnostic actions during the coronavirus outbreak (COVID-19) by issuing Emergency Use Authorizations (EUAs) to: Hologic for its Panther Fusion SARS-COV-2 Assay, and Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.

"Staff at FDA have been working nonstop to expedite the review and authorization of diagnostics during this public health emergency," said FDA Commissioner Stephen M. Hahn, M.D. "Our device center has been in continual contact with the medical device community, in particular diagnostic developers, since January -- providing technical assistance to test

developers to help facilitate the availability and distribution of tests so that health care professionals can accurately detect the COVID-19 virus. Since the beginning of this outbreak, more than 90 test developers have sought FDA guidance with the development and validation of tests they plan to bring through the EUA process. Additionally, more than 40 laboratories have notified us that they are testing or intend to begin testing soon under our new policy for laboratory-developed tests for this emergency. We stand ready to continue to support medical products in the pipeline to fight this virus.”

**Additional Resources:**

- [Novel Coronavirus](#)
- [Emergency Use Authorization](#)

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)



**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/18/2020 4:27:33 PM  
**To:** OC OL Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a35f07a0600471ba92352df4d23029f-OC OL Staff]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]; OO-OFBA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]  
**Subject:** Daily Coronavirus Legislative Recap - 3/18/20

Good afternoon,

Here is today's daily recap of legislative activity (new inquiries and outstanding activity).

Please see the tracker for the most up-to-date information: <http://sharepoint.fda.gov/orgs/OC-OL/corona/Shared%20Documents/Open-Closed%20COVID-19%20Congressional%20Inquiries%202.25.20.xlsx> (all inquiries we received today are below).

**NEW ITEMS**

| <u>Office</u>        | <u>Type</u> | <u>Subject</u>                                            | <u>OL Staff</u> |
|----------------------|-------------|-----------------------------------------------------------|-----------------|
| Hawaii Governor      | Question    | hand sanitizer                                            | IGA - Campbell  |
| Sen. Portman         | Question    | excess food from restaurants                              | Gras/Feingold   |
| Sen. Whitehouse      | Question    | process for importation of tests                          | Paulos          |
| Sen. Toomey          | Question    | EUAs for COVID-19 tests                                   | Paulos          |
| Sen. Young           | Question    | expedited medical device process                          | Paulos          |
| Sen. Feinstein       | Question    | FDA Hotline                                               | Paulos          |
| Sen. Burr            | Question    | LDT/IVD question                                          | Paulos          |
| E&C Majority         | Question    | Administration looking into 'self-swab' coronavirus tests | Paulos          |
| Rep. Burgess         | Question    | penicillin production                                     | Black/Paulos    |
| Washington state     | Question    | Hand sanitizer                                            | IGA - Campbell  |
| Follow up Rep. Pocan | Question    | State of WI in Severe shortage of re-agent and swabs      | OCA: Nguyen     |
| Sen. Schatz          | Question    | Chloroquine                                               | OCA: Price      |
| Rep. Harris          | Question    | Chloroquine Trials for COVID-19                           | OCA: Price      |

**IN PROGRESS**

| <u>Date</u> | <u>Office</u>        | <u>Type</u> | <u>Subject</u>                      | <u>OL Staff</u>                 |
|-------------|----------------------|-------------|-------------------------------------|---------------------------------|
| 2-24-20     | Sen. Josh Hawley     | Letter      | Medical supply chain                | Pennington/Lockeed/Paulos/Black |
| 2-26-20     | Sen. Tina Smith      | Letter      | Potential shortages                 | Pennington/Lockeed/Paulos/Black |
| 3-3-20      | Sens. Warren & Casey | Letter      | Fraudulent products                 | Pennington/Lockeed              |
| 3-4-20      | Rep. Crist           | Letter      | Coronavirus diagnostic availability | Pennington/Lockeed/Paulos       |
| 3-5-20      | Sen. Murray          | Letter      | COVID-19 testing                    | Pennington/Lockeed/Paulos       |
| 3-9-20      | Rep. Schakowsky,     | Letter      | COVID-19 testing affordability      | Pennington/Lockeed/Paulos       |



|         |                           |          |                                                                                                                                 |                                |
|---------|---------------------------|----------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|         | Doggett, & DeLauro        |          |                                                                                                                                 |                                |
| 3-9-20  | Rep. Meng +13             | Letter   | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Sen. Blumenthal           | Letter   | COVID-19 Warning Letters                                                                                                        | Pennington/Lockeed             |
| 3-10-20 | Rep. Higgins              | Letter   | Testing of COVID-19 samples                                                                                                     | Pennington/Lockeed/Paulos/Rath |
| 3-10-20 | Rep. Gabbard              | Letter   | Purchasing tests from South Korea and other testing questions                                                                   | Paulos/Lockeed                 |
| 3-10-20 | Sens. Warren & Murray     | Letter   | Including pregnant and lactating women in COVID-19 vaccine clinical trials                                                      | Aguilar/Lockeed                |
| 3-11-20 | Reps. Rose & Reed         | Letter   | Testing of COVID-19 Samples                                                                                                     | Paulos/Pennington/Lockeed      |
| 3-12-20 | Rep. Porter +80           | Letter   | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Thom Tillis          | Letter   | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Reps. Perlmutter & Veasey | Letter   | Antivirals                                                                                                                      | Black/Pennington               |
| 3-16-20 | E&C Oversight             | Question | Nasal Swabs                                                                                                                     | Hodnette/Lockeed/Pennington    |
| 3-16-20 | Sen. Gardner              | Letter   | EUAs/testing                                                                                                                    | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Blackburn            | Question | Drug inquiry                                                                                                                    | Black/Pennington/Lockeed       |
| 3-16-20 | Rep. Zeldin               | Letter   | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Beyer                | Letter   | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Carter               | Letter   | compounding pharmacies ability to make hand sanitizer and deal with shortages in drugs and OTC products during the COVID crisis | Black/Pennington               |

Thanks!

Caitlin

---

**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 3/19/2020 3:09:43 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]  
**Subject:** PREPARING TO ISSUE: Press Release, "Coronavirus (COVID-19) Update: FDA Continues to Facilitate Development of Treatments"  
**Attachments:** FINAL\_PR\_Chloroquine\_3.19.20-FOR PRN.docx

Hello,

The attached press release entitled, "Coronavirus (COVID-19) Update: FDA Continues to Facilitate Development of Treatments," will issue shortly on FDA's website.

Please do not distribute until the press release is live on our website here: <https://www.fda.gov/news-events/fda-newsroom/press-announcements>.

Thank you!

Michael

**Michael Felberbaum**  
*Senior Advisor*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-9548 / Cell: [REDACTED] (b)(6)  
[michael.felberbaum@fda.hhs.gov](mailto:michael.felberbaum@fda.hhs.gov)



---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/19/2020 3:59:27 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** Coronavirus (COVID-19) Update: FDA Continues to Facilitate Development of Treatments

Good afternoon -

The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention to the following announcement concerning Coronavirus (COVID-19).

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Best,

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)



## Coronavirus (COVID-19) Update: FDA Continues to Facilitate Development of Treatments

The U.S. Food and Drug Administration continues to play a critical role in the multifaceted all-of-government response to the COVID-19 pandemic, which includes, among other things, facilitating medical countermeasures to treat and prevent the disease, and surveilling the medical product and food supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary.

As part of those efforts, President Trump has directed the FDA to continue its work with the public and private sector to ensure the availability of potentially safe and effective life-saving drugs to patients who are in desperate need, including those infected with COVID-19.

The FDA has been working closely with other government agencies and academic centers that are investigating the use of the drug chloroquine, which is already approved for treating malaria, lupus and rheumatoid arthritis, to determine whether it can be used to treat patients with mild-to-moderate COVID-19 to potentially reduce the duration of symptoms, as well as viral shedding, which can help prevent the spread of disease. Studies are underway to determine the efficacy in using chloroquine to treat COVID-19.”

“President Trump’s aggressive response and bold actions to keep Americans safe from COVID-19 bought us precious time to advance therapeutics and other necessary tools,” said HHS Secretary Alex Azar. “Today’s actions show that HHS and the United States are leading the world in these efforts. Disseminating information about promising off-label uses of drugs we already have, investigating their effectiveness, and pursuing other therapeutics will help give American healthcare providers the tools they need to save lives. As we have always seen when America has faced a serious threat, American industry, academic institutions and government are coming together to deliver us what we need to win.”

The FDA wants to assure the American public that the agency continues to work with partners across the U.S. government and regulated industry to expedite the development and availability of critical medical products to prevent and treat this novel virus, including repurposing existing therapies that may help treat patients with COVID-19.

“As is true for most medical situations, the great American innovators in academia and industry have engaged with us about treatment options. We are extremely encouraged by the interest and promise in the development of the COVID-19-related therapies. We understand and recognize the urgency with which we are all seeking prevention and treatment options for COVID-19. FDA staff are working expeditiously on that front” said FDA Commissioner Stephen Hahn, M.D. “We also must ensure these products are effective; otherwise we risk treating patients with a product that might not work when they could have pursued other, more appropriate, treatments. At the same time, we will engage with domestic manufacturers to ramp up production of this product to mitigate any potential supply chain pressures. If clinical data suggests this product may be promising in treating COVID-19, we know there will be increased demand for it. We will take all steps to ensure chloroquine remains available for patients who take it to treat severe and life-threatening illnesses such as lupus.”

While there are no FDA-approved therapeutics or drugs to treat, cure or prevent COVID-19, there are several FDA-approved treatments that may help ease the symptoms from a supportive care perspective.

The FDA is working closely with innovators in their work to expedite these efforts, including leveraging scientific information about the virus and trials currently being conducted in other countries such as China, Japan, South Korea and Italy as well as in the U.S. Quickly after the emergence of this virus, the FDA began working directly with partners and innovators to foster the development of medical countermeasures against COVID-19, and we are continuing to provide regulatory flexibility, advice, guidance, and technical assistance. The FDA continues to work with interested sponsors to help expedite any additional clinical trials for COVID-19 medical countermeasures that may be appropriate. The FDA is able to, and has been, turning around requests very quickly to assist in initiating clinical trials.

For example, last month, the National Institutes of Health (NIH) began a randomized controlled trial for the treatment of COVID-19 patients with the investigational antiviral drug remdesivir. The FDA has been working with the drug sponsor, Gilead Sciences Inc., to find multiple pathways to both study the drug under the FDA’s investigational new drug requirements, and thus collect helpful data about the efficacy of the drug, as well as provide the drug to patients under emergency use. The FDA is committed to continuing to make use of its expanded access program to allow the emergency use of this product for those patients, when appropriate. To date, the agency has already granted about 250 patients access to this product. The data collected from the expanded access program may contribute to the agency’s understanding of the drug, but controlled clinical trials are needed to determine if it safe and effective for the treatment of COVID-19 infection.

The FDA’s efforts to facilitate the development of these therapies are squarely focused on ensuring these medical countermeasures meet the agency’s world-respected gold standard, relying on data from adequate and well-controlled trials to most efficiently determine if an experimental treatment can safely and effectively benefit patients.

Innovators are looking at products in a variety of areas, including the assessment of antiviral drugs that might treat the specific virus, as well as host targets, such as interleukin-6 (IL-6) receptor inhibitors that may be helpful in reducing lung inflammation and improving lung function in COVID-19 patients, thereby potentially slowing the progression of severe respiratory symptoms. Regeneron Pharmaceuticals Inc. has announced the initiation of a randomized controlled clinical trial of sarilumab, an antibody to the IL-6 receptor, to assess whether the modification of the inflammatory response by this treatment provides benefit to COVID-19 patients.

There’s also interest in evaluating whether therapies, such as convalescent plasma and hyperimmune globulin, antibody-rich blood products that are taken from blood donated by people who have recovered from the virus, could shorten the length, or lessen the severity, of the illness. The FDA is taking the lead on an urgent cross-government approach to facilitate the development of all of these products. Facilitating the ultimate widespread use and availability of safe and effective medical countermeasures is critical for a number of reasons, including

that reducing the severity and duration of respiratory or other symptoms through medical treatments could help lessen the burden on medical personnel, equipment, and facilities.

At the same time, the FDA will continue work to facilitate the development of treatment options in the near-term, the agency is also working with interagency partners, product developers, and international public health organizations to expedite the development of vaccines to the greatest extent possible. In fact, earlier this week, NIH announced the start of a Phase 1 clinical trial in Seattle in 45 healthy adult volunteers to test the safety of an investigational vaccine designed to protect against COVID-19 infection. The FDA intends to use all of the regulatory flexibility granted to it by Congress to ensure the most efficient and timely development of vaccines to fight COVID-19.

As agency staff work around the clock to facilitate prevention and treatment options, it's extremely important for everyone to know that people may try to make claims about products that are not approved - and don't have data supporting efficacy - in preventing, treating or diagnosing COVID-19. The FDA is closely monitoring the market to combat these products with fraudulent claims. It is unacceptable that anyone would take advantage of Americans during this public health crisis, and the FDA wants to make sure everyone knows what legitimate products are being developed.

The FDA remains steadfast in helping to foster the development of safe and effective medical countermeasures and ensuring they are available as quickly as possible to protect public health and safeguarding Americans from fraudulent products claiming to prevent, treat, or diagnose COVID-19 as part of the agency's around-the-clock response to this outbreak.

**Additional Resources:**

- [Coronavirus Disease \(COVID-19\)](#)
- [What are Medical Countermeasures?](#)

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/19/2020 4:49:57 PM  
**To:** OC OL Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a35f07a0600471ba92352df4d23029f-OC OL Staff]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]; OO-OFBA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]  
**Subject:** Daily Coronavirus Legislative Recap - 3/19/20

Good afternoon,

Here is today's daily recap of legislative activity (new inquiries and outstanding activity).

Please see the tracker for the most up-to-date information: <http://sharepoint.fda.gov/orgs/OC-OL/corona/Shared%20Documents/Open-Closed%20COVID-19%20Congressional%20Inquiries%202.25.20.xlsx> (all inquiries we received today are below).

**NEW ITEMS**

- OL: Rep. Horsford question re COVID-19 testing
- OL: Rep. Fleischmann question re EUAs
- OL: Rep. McHenry questions re furniture industry helping make masks, gowns, etc.
- OL: Sen. Gardner questions re inspections
- OL: Rep. Ferguson question re ventilators
- OL: Sen. Capito question re supply chain
- OL: Rep. Kind letter re COVID-19 testing
- OL: Rep. DesJarlais questions re inspections
- OL: Sen. Smith question re supply chain
- OL: Rep. Keller question re masks
- OL: Rep. Balderson question re PPE
- OL: Sen. Shaheen question re HVAC Air Purifier System
- OL: Remdesizir question from Sen. Toomey
- OL: Rep. O'Halleran question re testing kits
- OL: Senate HELP question re DoD assistance with obtaining testing materials
- OL: Rep. Lamborn question re COVID-19 testing
- OL: Rep. Gooden question re hand sanitizers
- OL: Rep. Yarmuth question re hand sanitizers
- OL: Rep. Walorski question re hand sanitizers
- OCA: Sen. Lankford question re testing kits
- OCA: Rep. Meng question re PPE
- OCA: Sen. Shelby question re hand sanitizer
- IGA: National Governor's Association questions re drug supply chain and diagnostics

**IN PROGRESS**

| Date    | Office               | Type   | Subject              | OL Staff                        |
|---------|----------------------|--------|----------------------|---------------------------------|
| 2-24-20 | Sen. Josh Hawley     | Letter | Medical supply chain | Pennington/Lockeed/Paulos/Black |
| 2-26-20 | Sen. Tina Smith      | Letter | Potential shortages  | Pennington/Lockeed/Paulos/Black |
| 3-3-20  | Sens. Warren & Casey | Letter | Fraudulent products  | Pennington/Lockeed              |

|         |                                         |           |                                                                                                                                 |                                |
|---------|-----------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 3-4-20  | Rep. Crist                              | Letter    | Coronavirus diagnostic availability                                                                                             | Pennington/Lockeed/Paulos      |
| 3-5-20  | Sen. Murray                             | Letter    | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Rep. Schakowsky, Doggett, & DeLauro     | Letter    | COVID-19 testing affordability                                                                                                  | Pennington/Lockeed/Paulos      |
| 3-9-20  | Rep. Meng +13                           | Letter    | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Sen. Blumenthal                         | Letter    | COVID-19 Warning Letters                                                                                                        | Pennington/Lockeed             |
| 3-10-20 | Rep. Higgins                            | Letter    | Testing of COVID-19 samples                                                                                                     | Pennington/Lockeed/Paulos/Rath |
| 3-10-20 | Rep. Gabbard                            | Letter    | Purchasing tests from South Korea and other testing questions                                                                   | Paulos/Lockeed                 |
| 3-10-20 | Sens. Warren & Murray                   | Letter    | Including pregnant and lactating women in COVID-19 vaccine clinical trials                                                      | Aguilar/Lockeed                |
| 3-11-20 | Reps. Rose & Reed                       | Letter    | Testing of COVID-19 Samples                                                                                                     | Paulos/Pennington/Lockeed      |
| 3-12-20 | Rep. Porter +80                         | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Thom Tillis                        | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Reps. Perlmutter & Veasey               | Letter    | Antivirals                                                                                                                      | Black/Pennington               |
| 3-16-20 | E&C Oversight                           | Question  | Nasal Swabs                                                                                                                     | Hodnette/Lockeed/Pennington    |
| 3-16-20 | Sen. Gardner                            | Letter    | EUAs/testing                                                                                                                    | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Blackburn                          | Question  | Drug inquiry                                                                                                                    | Black/Pennington/Lockeed       |
| 3-16-20 | Rep. Zeldin                             | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Beyer                              | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Carter                             | Letter    | compounding pharmacies ability to make hand sanitizer and deal with shortages in drugs and OTC products during the COVID crisis | Black/Pennington               |
| 3-18-20 | HGSAC Minority                          | Questions | Medical product supply chain                                                                                                    | Hodnette                       |
| 3-18-20 | E&C                                     | Questions | Foreign Inspections                                                                                                             | Howard/Rosebraugh              |
| 3-19-20 | Senate HELP bipartisan & Sen. McConnell | Questions | Food & Feed Inspection and Food Waste Q&A                                                                                       | Colonus/Feingold/Lockeed       |
| 3-19-20 | National Governors Association          | Questions | Drug supply chain and diagnostics                                                                                               | Campbell                       |
| 3-19-20 | Sen. Pat Toomey                         | Question  | Remdesivir                                                                                                                      | Black/Pennington               |
| 3-19-20 | E&C                                     | Question  | Follow up questions from 3/19 E&C Briefing                                                                                      | Black/Pennington               |
| 3-19-20 | Congressional fellow                    | Question  | IND                                                                                                                             | Black/Pennington               |

Thanks!

Caitlin



---

**From:** Gras, Ruth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=896294988DDC451F93B1073F119943AF-RUTH.GRAS]  
**Sent:** 3/19/2020 9:19:48 PM  
**To:** Tiffany Waddell -GOV- [tiffany.waddell@maryland.gov]  
**Subject:** RE: COVID-19 Social Distancing & Travel Restrictions - Impact on Blood/Plasma Donations and Food Workers

Many thanks for your response. We will be sending you an invitation to a call tomorrow at 11:30 AM with Dr. Peter Marks, CBER Director, to discuss this important issue.

Thanks again and stay well.

Best regards,  
Ruth Gras  
FDA Intergovernmental Affairs Team

**From:** Tiffany Waddell -GOV- <tiffany.waddell@maryland.gov>  
**Sent:** Thursday, March 19, 2020 9:08 PM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** Re: COVID-19 Social Distancing & Travel Restrictions - Impact on Blood/Plasma Donations and Food Workers

Good evening Ruth,  
Thank you so much for sharing. Governor Hogan spoke with the American Red Cross Earlier today and will begin messaging blood donation in the coming days. I will also share your FDA statement with the team.

Best regards, Tiffany

On Thu, Mar 19, 2020 at 7:26 PM Gras, Ruth <Ruth.Gras@fda.hhs.gov> wrote:

Dear Ms. Judah and Ms. Waddell:

We want to bring to your attention two issues of critical importance related to implementation of social distancing, travel restrictions, and other measures put into place to respond to the COVID-19 pandemic.

**Blood Donation:**

There has been a dramatic reduction in blood donation, including cancellation of blood drives, during the COVID-19 pandemic. We have also heard concerns about collections of source plasma, which is a critical ingredient in biologics used to treat many serious diseases, and is also currently being used to develop potential treatments for COVID-19 infections.

**Food Processing Workers:**

We are aware of a recently reported incident where food processing facility workers were stopped on the way to their jobs due to curfew/shelter-in-place orders.

**As you develop your local response to the COVID-19 pandemic, including any planned or potential travel restrictions, we urge you to consider the continued operation of blood and source plasma collection centers, including travel to the centers by individuals intending to donate. We also urge you to consider ways to enable food and beverage employees, who are considered part of a critical business sector, to make it to their workplace.**

(See also recent guidance from the Director of the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA), entitled *MEMORANDUM ON IDENTIFICATION OF ESSENTIAL CRITICAL INFRASTRUCTURE WORKERS DURING COVID-19 RESPONSE.*)

We would appreciate your help, within your jurisdiction, to ensure awareness, coordination and communication with appropriate law enforcement agencies, state/local emergency operation centers, and with other stakeholders, so that those operating blood and plasma collection centers as well as donors – who are contributing immeasurably to the country's preparedness – can travel to and from blood and source plasma collection centers. We also hope that you will reiterate our messages in the attached FDA Statement from CBER Director Peter Marks, M.D. about the importance of blood and plasma donation and the measures that are being taken so that individuals can donate safely during this critical time. *You will receive more information about a FDA state/local call on this issue shortly.*

We would also appreciate your assistance in ensuring that the same awareness, coordination and communication happens with the appropriate state/local agencies so that human and animal food workers – who are part of the critical infrastructure – will be allowed to travel to and from their jobs. We are also working with food industry stakeholders to ensure their food workers have appropriate identification.

If you have any questions, please contact FDA's Intergovernmental Affairs team at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

--

---

**Tiffany Waddell**

Senior Advisor & Director, Federal Relations

Office of the Governor

444 N. Capitol Street NW Suite 311

Washington, DC 20001

[tiffany.waddell@maryland.gov](mailto:tiffany.waddell@maryland.gov)

(202) 624-1432 (O)

(b)(6) (M)

Website | Facebook | Twitter

---

**From:** Gras, Ruth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=896294988DDC451F93B1073F119943AF-RUTH.GRAS]  
**Sent:** 3/20/2020 8:37:22 AM  
**To:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** FW: [FINAL/CONFIRMED] Today's FDA 50-State Conference Call, Coronavirus (COVID-19) Update: Blood Donations, Friday, March 20, 2020, 11:30 am – 12:00 Noon EDT  
**Attachments:** 20200320\_ TPs for 50 state call re blood supply FINAL.docx

---

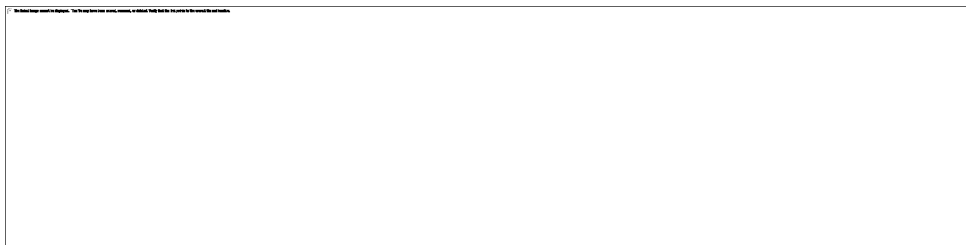
**From:** Gras, Ruth  
**Sent:** Friday, March 20, 2020 8:36 AM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>  
**Subject:** [FINAL/CONFIRMED] Today's FDA 50-State Conference Call, Coronavirus (COVID-19) Update: Blood Donations, Friday, March 20, 2020, 11:30 am – 12:00 Noon EDT

Dr. Marks will be doing a 50-state call on the COVID-19 blood supply concerns today at 11:30 AM. A copy of the final cleared talking points is attached, and the invitation appears below.

---

**From:** U.S. Food and Drug Administration <[fda@info.fda.gov](mailto:fda@info.fda.gov)>  
**Sent:** Thursday, March 19, 2020 10:55 PM  
**To:** Norris, Gary <[Gary.Norris@fda.hhs.gov](mailto:Gary.Norris@fda.hhs.gov)>  
**Subject:** IMPORTANT NOTICE – FDA 50-State Conference Call, Coronavirus (COVID-19) Update: Blood Donations, Friday, March 20, 2020, 11:30 am – 12:00 Noon EDT

If your email program has trouble displaying this email, view it as a [web page](#).



March 19, 2020

**IMPORTANT NOTICE: 50-STATE CONFERENCE CALL**

This call is intended for federal, state, local, tribal, and territorial health department and public health officials. Please do not post this message outside of your Agency.

Dear Colleagues,

The U.S. Food and Drug Administration (FDA) will host a 50-State conference call with Dr. Peter Marks, Director of FDA's Center for Biologics Evaluation and Research, on Friday, March 20, 2020 at 11:30 am EDT, regarding efforts to help ensure an adequate blood supply during the COVID-19 pandemic.

**50-STATE CONFERENCE CALL INFORMATION**

Date/Time: **Friday, March 20, 2020, 11:30 am – 12:00 Noon EDT**

Phone Number:

**(b)(6)**

Participant Passcode:

*NOTE: After you have typed in the phone number and numerical participant passcode above using your keypad, you will be asked by the automated voice capture system to verbally provide your name and organization slowly and clearly with spelling before being placed in the audio portion of the conference call. Please do not enter your name and organization using your phone keypad – you must verbally provide your name and organization (ensure that your mute button is off).*

As highlighted in today's [press release](#), there has been a dramatic reduction in blood donation due to implementation of social distancing, travel restrictions, and cancellation of blood drives during the COVID-19 pandemic. We have also heard concerns about collections of source plasma, which is a critical ingredient in biologics used to treat many serious diseases, and is also currently being used to develop potential treatments for COVID-19 infections.

As you develop your local response to the COVID-19 pandemic, including any planned or potential travel restrictions, we urge you to consider the continued operation of blood and source plasma collection centers, including travel to the centers by individuals intending to donate, because of the essential nature of these activities. We would appreciate your help, within your respective agencies and jurisdictions, to ensure awareness, coordination and communication with appropriate law enforcement agencies, state/local emergency operation centers, and with other stakeholders, so that those operating blood and plasma collection centers as well as donors – who are contributing immeasurably to the country's preparedness - can travel to and from blood and source plasma collection centers.

We also hope that you will reiterate our messages in the press release about the importance of blood and plasma donation and the measures that are being taken so that individuals can donate safely during this critical time.

This message is being broadcast by the Division of Communications in FDA's Office of Regulatory Affairs (ORA).

Thank you,

FDA/ORA

Office of Communications and Project Management

Division of Communications

Mailbox: DivComm-ORA@fda.hhs.gov



U.S. Food and Drug Administration

10903 New Hampshire Avenue, Silver Spring, MD 20993

1-888-INFO-FDA (1-888-463-6332)

[Privacy Policy](#) | [www.fda.gov](http://www.fda.gov)

[Manage Preferences](#) or [Unsubscribe](#) from this List | [Unsubscribe](#) from all Email Lists



---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/20/2020 9:57:47 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health

**Importance:** High

Good morning-

The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention to the following announcement concerning Coronavirus (COVID-19).

The Agency has issued two guidance documents to communicate its policy for the temporary manufacture of certain alcohol-based hand sanitizer products.

See below for links to the guidance.

We hope this information is helpful to you.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Best,

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)



## **Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health**

As part of the U.S. Food and Drug Administration's ongoing commitment to address the coronavirus (COVID-19) pandemic, the agency has issued two guidance documents to communicate its policy for the temporary manufacture of certain alcohol-based hand sanitizer products. These guidance documents will be in effect for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.

**"We are aware of significant supply disruptions for alcohol-based hand sanitizers. Many manufacturers make hand sanitizers, and several have indicated that they are working to increase supply,"** said FDA Commissioner Stephen M. Hahn, M.D. **"In the meantime, these**

**guidances provide flexibility to help meet demand during this outbreak. We will continue to work with manufacturers, compounders, state boards of pharmacy and the public to increase the supply of alcohol-based hand sanitizer available to Americans.”**

Because of an increased demand for alcohol-based hand sanitizers during the COVID-19 pandemic, there have been reports of some consumers attempting to make hand sanitizers for personal use. The agency lacks information on the methods being used to prepare such products and whether they are safe for use on human skin.

The guidance *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*, is immediately in effect and outlines that the agency does not intend to take action against manufacturing firms that prepare alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs during this ongoing public health emergency as described in the guidance .

The second guidance, *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*, is in effect for the temporary compounding of certain alcohol-based hand sanitizers by pharmacists in state-licensed pharmacies or federal facilities and registered outsourcing facilities. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a tailor-made medication. The temporary policy outlined by the agency does not require compounders to obtain a patient-specific prescription.

The FDA’s guidance documents apply only to handrub products prepared using the United States Pharmacopoeia or Food Chemical Codex grade ingredients specifically described in the guidance, consistent with World Health Organization recommendations. The guidance documents also discuss product labeling and certain manufacturing methods and reporting requirements, such as that manufacturers must have a way to accept and submit adverse event reports to FDA for any products they manufacture.

The agency realizes that manufacturers and compounders will need time to ramp up production as they obtain the ingredients needed to make these hand sanitizers. During this time the FDA will work to assist them as they develop hand sanitizers to make available for the American public.

#### Additional Resources:

- [FDA: Novel coronavirus \(COVID-19\)](#)
- [Human Drug Compounding](#)

---

**From:** Gras, Ruth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=896294988DDC451F93B1073F119943AF-RUTH.GRAS]  
**Sent:** 3/20/2020 10:12:32 AM  
**To:** Gras, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=896294988ddc451f93b1073f119943af-Ruth.Gras]  
**CC:** Gras, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=896294988ddc451f93b1073f119943af-Ruth.Gras]  
**Subject:** 50-State FDA Conference Call Today: COVID-19 Social Distancing & Travel Restrictions - Impact on Blood/Plasma Donations

Good morning,

FDA's Intergovernmental Affairs Team would like to share this invitation for an FDA 50-state conference call, taking place at 11:30 this morning, regarding efforts to help ensure an adequate blood supply during the COVID-19 pandemic. Dr. Peter Marks, Director of FDA's Center for Biologics Evaluation and Research, will be the speaker.

If you have any questions, please contact FDA's Intergovernmental Affairs team at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

If your email program has trouble displaying this email, view it as a [web page](#).

---

March 19, 2020

**IMPORTANT NOTICE: 50-STATE CONFERENCE CALL**

This call is intended for federal, state, local, tribal, and territorial health department and public health officials. Please do not post this message outside of your Agency.

Dear Colleagues,

The U.S. Food and Drug Administration (FDA) will host a 50-State conference call with Dr. Peter Marks, Director of FDA's Center for Biologics Evaluation and Research, on Friday, March 20, 2020 at 11:30 am EDT, regarding efforts to help ensure an adequate blood supply during the COVID-19 pandemic.

**50-STATE CONFERENCE CALL INFORMATION**

Date/Time: **Friday, March 20, 2020, 11:30 am – 12:00 Noon EDT**

Phone Number: **(800) 857-5383**

Participant Passcode: **(b)(6)**

*NOTE: After you have typed in the phone number and numerical participant passcode above using your keypad, you will be asked by the automated voice capture system to verbally provide your name and organization slowly and clearly with spelling before being placed in the audio portion of the conference call. Please do not enter your name and organization using your phone keypad – you must verbally provide your name and organization (ensure that your mute button is off).*

As highlighted in today's [press release](#), there has been a dramatic reduction in blood donation due to implementation of social distancing, travel restrictions, and cancellation of blood drives during the COVID-19 pandemic. We have also heard concerns about



collections of source plasma, which is a critical ingredient in biologics used to treat many serious diseases, and is also currently being used to develop potential treatments for COVID-19 infections.

As you develop your local response to the COVID-19 pandemic, including any planned or potential travel restrictions, we urge you to consider the continued operation of blood and source plasma collection centers, including travel to the centers by individuals intending to donate, because of the essential nature of these activities. We would appreciate your help, within your respective agencies and jurisdictions, to ensure awareness, coordination and communication with appropriate law enforcement agencies, state/local emergency operation centers, and with other stakeholders, so that those operating blood and plasma collection centers as well as donors – who are contributing immeasurably to the country’s preparedness - can travel to and from blood and source plasma collection centers.

We also hope that you will reiterate our messages in the press release about the importance of blood and plasma donation and the measures that are being taken so that individuals can donate safely during this critical time.

This message is being broadcast by the Division of Communications in FDA's Office of Regulatory Affairs (ORA).

Thank you,

FDA/ORA  
Office of Communications and Project Management  
Division of Communications  
Mailbox: DivComm-ORA@fda.hhs.gov

---

U.S. Food and Drug Administration  
10903 New Hampshire Avenue, Silver Spring, MD 20993  
1-888-INFO-FDA (1-888-463-6332)

[Privacy Policy](#) | [www.fda.gov](http://www.fda.gov)

[Manage Preferences](#) or [Unsubscribe from this List](#) | [Unsubscribe from all Email Lists](#)

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/20/2020 3:13:06 PM  
**To:** OC OL Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a35f07a0600471ba92352df4d23029f-OC OL Staff]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]; OO-OFBA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]  
**Subject:** Daily Coronavirus Legislative Recap - 3/20/20

Good afternoon,

Here is today's daily recap of legislative activity (new inquiries and outstanding activity).

Please see the tracker for the most up-to-date information: <http://sharepoint.fda.gov/orgs/●C-●L/corona/Shared%20Documents/Open-Closed%20COVID-19%20Congressional%20Inquiries%202.25.20.xlsx> (all inquiries we received today are below).

**NEW ITEMS**

- OL: Rep. Yarmuth follow up questions re hand sanitizers
- OL: Rep. Keller question on connecting manufacturing companies with FDA
- OL: Rep. Palmer question on coronavirus testing kit manufacturer in district needs some guidance on employee testing and how that impacts their production practices
- OL: Rep. Porter question on at home testing kit approvals
- OL: Rep. Deutch question on biotech
- OL: Sen. Brown questions re importation of masks
- OL: Sen. Crapo question re PPE
- OL: Rep. Amodei question re testing kits
- OL: Rep. Reed question re Regeneron
- OL: Rep. Barr question re Plaquenil drug shortage
- OL: Rep. Hoyer question re Qiagen
- OL: Rep. Suozzi question re importation of masks
- OL: Rep. Stivers question re diagnostics
- OL: Rep. Conaway question re ventilators
- OL: Rep. Huizenga question re diagnostics
- IGA: Utah State question on Hydroxychloroquine / chloroquine shortage

**IN PROGRESS**

| <u>Date</u> | <u>Office</u>        | <u>Type</u> | <u>Subject</u>                      | <u>OL Staff</u>                 |
|-------------|----------------------|-------------|-------------------------------------|---------------------------------|
| 2-24-20     | Sen. Josh Hawley     | Letter      | Medical supply chain                | Pennington/Lockeed/Paulos/Black |
| 2-26-20     | Sen. Tina Smith      | Letter      | Potential shortages                 | Pennington/Lockeed/Paulos/Black |
| 3-3-20      | Sens. Warren & Casey | Letter      | Fraudulent products                 | Pennington/Lockeed              |
| 3-4-20      | Rep. Crist           | Letter      | Coronavirus diagnostic availability | Pennington/Lockeed/Paulos       |
| 3-5-20      | Sen. Murray          | Letter      | COVID-19 testing                    | Pennington/Lockeed/Paulos       |
| 3-9-20      | Rep. Schakowsky,     | Letter      | COVID-19 testing affordability      | Pennington/Lockeed/Paulos       |

|         |                                         |           |                                                                                                                                 |                                |
|---------|-----------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
|         | Doggett, & DeLauro                      |           |                                                                                                                                 |                                |
| 3-9-20  | Rep. Meng +13                           | Letter    | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Sen. Blumenthal                         | Letter    | COVID-19 Warning Letters                                                                                                        | Pennington/Lockeed             |
| 3-10-20 | Rep. Higgins                            | Letter    | Testing of COVID-19 samples                                                                                                     | Pennington/Lockeed/Paulos/Rath |
| 3-10-20 | Rep. Gabbard                            | Letter    | Purchasing tests from South Korea and other testing questions                                                                   | Paulos/Lockeed                 |
| 3-10-20 | Sens. Warren & Murray                   | Letter    | Including pregnant and lactating women in COVID-19 vaccine clinical trials                                                      | Aguilar/Lockeed                |
| 3-11-20 | Reps. Rose & Reed                       | Letter    | Testing of COVID-19 Samples                                                                                                     | Paulos/Pennington/Lockeed      |
| 3-12-20 | Rep. Porter +80                         | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Thom Tillis                        | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Reps. Perlmutter & Veasey               | Letter    | Antivirals                                                                                                                      | Black/Pennington               |
| 3-16-20 | E&C Oversight                           | Question  | Nasal Swabs                                                                                                                     | Hodnette/Lockeed/Pennington    |
| 3-16-20 | Sen. Gardner                            | Letter    | EUAs/testing                                                                                                                    | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Blackburn                          | Question  | Drug inquiry                                                                                                                    | Black/Pennington/Lockeed       |
| 3-16-20 | Rep. Zeldin                             | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Beyer                              | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Carter                             | Letter    | compounding pharmacies ability to make hand sanitizer and deal with shortages in drugs and OTC products during the COVID crisis | Black/Pennington               |
| 3-18-20 | HGSAC Minority                          | Questions | Medical product supply chain                                                                                                    | Hodnette                       |
| 3-18-20 | E&C                                     | Questions | Foreign Inspections – f/u from 3/18 briefing                                                                                    | Howard/Rosebraugh              |
| 3-19-20 | Senate HELP bipartisan & Sen. McConnell | Questions | Food & Feed Inspection and Food Waste Q&A                                                                                       | Colonius/Feingold/Lockeed      |
| 3-19-20 | National Governors Association          | Questions | Drug supply chain and diagnostics                                                                                               | Campbell                       |
| 3-19-20 | Sen. Pat Toomey                         | Question  | Remdesivir                                                                                                                      | Black/Pennington               |
| 3-19-20 | E&C                                     | Question  | Follow up questions from 3/19 E&C Briefing                                                                                      | Black/Pennington               |
| 3-19-20 | Congressional fellow                    | Question  | IND                                                                                                                             | Black/Pennington               |

Thanks!

Caitlin

---

**From:** Acosta, Christine@DCA [Christine.Acosta@dca.ca.gov]  
**Sent:** 3/20/2020 4:29:02 PM  
**To:** Jafary, Mariza [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f56e64e61d954745b80d703da555cf51-Mariza.Jafa]; Berry, Thomas R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce7d7b82a2d0494db7b5dcafb22c1d21-TBERRY]; Anderson, Kathleen R [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2faa017c38542a28f143be82104bf9d-ANDERSONK]; Porter, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5f87e86f7e8421ab5dc6f4c7e6a3d58-Steven.Port]; Elwood, Will [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Fortney, Russell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86db918272164d9ea5d88d0dc8721f10-FORTNEYR]; Ju, Ruey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d776f3aaed684b479da82edcc420f902-Ruey.Ju]  
**CC:** Sodergren, Anne@DCA [Anne.Sodergren@dca.ca.gov]  
**Subject:** FW: Hydroxychloroquine Tablets supplier

**Importance:** High

FDA;

A board member received the following email. We have been able to determine that this company is able to import, we suspect not.

However, our pharmacy are not able to get this drug and are desperately reaching out to us for direction on this medication.

Please send me to whomever can help!!

**California STRONG!**

For the most updated COVID-19 waivers: [https://pharmacy.ca.gov/licensees/emergency\\_declaration.shtml](https://pharmacy.ca.gov/licensees/emergency_declaration.shtml)

Thank you,



**Christine Acosta PharmD**, Supervising Inspector  
California State Board of Pharmacy  
(619) 818-7255 | FAX (760) 796-4610 | [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)  
**Be Aware and Take Care: Talk to your Pharmacist!**

Useful links:

2020 law book: [https://www.pharmacy.ca.gov/laws\\_regs/lawbook.pdf](https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf)

**Compounding Requirements Pending USP Appeals policy statement:**

[https://www.pharmacy.ca.gov/licensees/compounding\\_policy\\_statement.pdf](https://www.pharmacy.ca.gov/licensees/compounding_policy_statement.pdf)

---

**From:** Sodergren, Anne@DCA <Anne.Sodergren@dca.ca.gov>  
**Sent:** Friday, March 20, 2020 1:18 PM  
**To:** Acosta, Christine@DCA <Christine.Acosta@dca.ca.gov>  
**Subject:** FW: Hydroxychloroquine Tablets

Do you have some FDA magic in you?



**Anne Sodergren**, Executive Officer  
California State Board of Pharmacy  
(916) 518-3110 | FAX (916) 574-8618 | [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)  
**Be Aware and Take Care: Talk to your Pharmacist!**

**From:** Jignesh Patel <(b)(6)>  
**Sent:** Friday, March 20, 2020 1:15 PM  
**To:** Sodergren, Anne@DCA <(b)(6)>  
**Subject:** Fwd: Hydroxychloroquine Tablets

[EXTERNAL]: (b)(6)

CAUTION: THIS EMAIL ORIGINATED OUTSIDE THE DEPARTMENT OF CONSUMER AFFAIRS!  
DO NOT: click links or open attachments unless you know the content is safe.  
NEVER: provide credentials on websites via a clicked link in an Email.

---

Anne

See email below from Acme, they can ship a lot in (b)(4) and can manufacture more of needed.

They have a contact in United States as well. If FDA gives a go state will have the meds by Wed or Thu.

Thanks

Jig

----- Forwarded message -----

From: **Prashant Kumar** <[prashant@acmegrp.in](mailto:prashant@acmegrp.in)>  
CC: Sid Acme Group <[sid@acmegrp.in](mailto:sid@acmegrp.in)>  
D

Dear Sir,

We would like to inform you that we are one of the leading quality manufacturers in india for Hydroxychloroquine sulphate tablets.  
Ours is a state of the art facility with WHO GMP accreditation.

We are in the business of manufacturing of pharmaceutical formulations since more than three and half decade . Over the years we have handled and manufactured brands for some of the leading National and Multinational companies including that for (b)(4).  
(We have the capacity to produce (b)(4) (b)(4) With our resources we can ship (b)(4) with the help of government of California state.

Kindly let us know of your requirement in this unfortunate hour of crisis to help the people of California.

For price and commercial you can reach out to our counterparts in USA Mr. Sid Patel on 813-966-3195 813

Thanks

Prashant -966-3195

--

Prashant Kumar,

Acme Lifetech LLP,

701,Akshar Stadia,

Opposite Symphony House, Near Allen Institute,

B/h Gurudwara

S G Road

Ahmedabad-380015

Mobile: (b)(6)

Phone: +91 79 48907524/48907624

7043335168

e-mail: prashant@acmegrp.in

---

**From:** Kahn, Jeremy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B98D36D2C1F4AE795140B68DE7B37F7-JEREMY.KAHN]  
**Sent:** 3/20/2020 5:41:24 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; Garrett, Ulysses [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=122e0d937fed4cb1af3369cde17766db-Ulysses.Gar]  
**Subject:** Preparing to Issue: Coronavirus (COVID-19) Update: Update: FDA alerts Consumers about Unauthorized Fraudulent COVID-19 Test Kits  
**Attachments:** 20200319-PR-COVID-19 Fradulent Test Kits FINAL wmeta.docx

OMA is preparing to issue the following Press Release: Coronavirus (COVID-19) Update: FDA alerts Consumers about Unauthorized Fraudulent COVID-19 Test Kits

This should post here within the next 30 minutes.

Thank you,  
--Jeremy

**Jeremy Kahn**  
*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 301-796-8671  
[jeremy.kahn@fda.hhs.gov](mailto:jeremy.kahn@fda.hhs.gov)



**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/23/2020 5:03:47 PM  
**To:** OC OL Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a35f07a0600471ba92352df4d23029f-OC OL Staff]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]; OO-OFBA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]  
**Subject:** Daily Coronavirus Legislative Recap - 3/23/20

Good afternoon,

Here is today's daily recap of legislative activity (new inquiries and outstanding activity).

Please see the tracker for the most up-to-date information: <http://sharepoint.fda.gov/orgs/OC-OL/corona/Shared%20Documents/Open-Closed%20COVID-19%20Congressional%20Inquiries%202.25.20.xlsx> (all inquiries we received today are below).

**NEW ITEMS**

- OL: Sen. Cruz letter re drug approvals
- OL: Sen. Cruz inquiry re BGI EUA
- OL: Rep. Phil Roe inquiry re availability of hydroxychloroquine
- OL: Sen. Manchin questions re hand sanitizer and vaccine trials
- OL: Rep. Posey questions re ventilators and respirators
- OL: Sen. Blackburn question re hand sanitizer
- OL: Rep. Chip Roy question re PPE and testing capabilities
- OL: Rep. Lizzie Fletcher question re COVID-19 test
- OL: Rep. Guthrie question re hand sanitizer
- OL: Rep. Joyce question re hand sanitizer
- OL: Rep. Titus question re PPE specifications
- OL: Rep. Trahan question re EUA
- OL: Rep. Gottenheimer question re Remdesivir
- OL: Rep. DeFazio question re PPE specifications
- OL: Rep. McNerney question re PPE specifications
- OL: Rep. Castor question re PPE specifications
- OL: Rep. Hartzeler question re PPE specifications
- OL: Sen. Udall question re ventilators
- OL: Rep. Keller question re hydroxychloroquine
- OL: Rep. Emmer question re software for drug shortage monitoring
- IGA: Hawaii Governor's office question re hand sanitizer
- OCA: Rep. Tim Ryan inquiry re PPE

**IN PROGRESS**

| <u>Date</u> | <u>Office</u>        | <u>Type</u> | <u>Subject</u>       | <u>OL Staff</u>                 |
|-------------|----------------------|-------------|----------------------|---------------------------------|
| 2-24-20     | Sen. Josh Hawley     | Letter      | Medical supply chain | Pennington/Lockeed/Paulos/Black |
| 2-26-20     | Sen. Tina Smith      | Letter      | Potential shortages  | Pennington/Lockeed/Paulos/Black |
| 3-3-20      | Sens. Warren & Casey | Letter      | Fraudulent products  | Pennington/Lockeed              |



|         |                                         |           |                                                                                                                                 |                                |
|---------|-----------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 3-4-20  | Rep. Crist                              | Letter    | Coronavirus diagnostic availability                                                                                             | Pennington/Lockeed/Paulos      |
| 3-5-20  | Sen. Murray                             | Letter    | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Rep. Schakowsky, Doggett, & DeLauro     | Letter    | COVID-19 testing affordability                                                                                                  | Pennington/Lockeed/Paulos      |
| 3-9-20  | Rep. Meng +13                           | Letter    | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Sen. Blumenthal                         | Letter    | COVID-19 Warning Letters                                                                                                        | Pennington/Lockeed             |
| 3-10-20 | Rep. Higgins                            | Letter    | Testing of COVID-19 samples                                                                                                     | Pennington/Lockeed/Paulos/Rath |
| 3-10-20 | Rep. Gabbard                            | Letter    | Purchasing tests from South Korea and other testing questions                                                                   | Paulos/Lockeed                 |
| 3-10-20 | Sens. Warren & Murray                   | Letter    | Including pregnant and lactating women in COVID-19 vaccine clinical trials                                                      | Aguilar/Lockeed                |
| 3-11-20 | Reps. Rose & Reed                       | Letter    | Testing of COVID-19 Samples                                                                                                     | Paulos/Pennington/Lockeed      |
| 3-12-20 | Rep. Porter +80                         | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Thom Tillis                        | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Reps. Perlmutter & Veasey               | Letter    | Antivirals                                                                                                                      | Black/Pennington               |
| 3-16-20 | E&C Oversight                           | Question  | Nasal Swabs                                                                                                                     | Hodnette/Lockeed/Pennington    |
| 3-16-20 | Sen. Gardner                            | Letter    | EUAs/testing                                                                                                                    | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Blackburn                          | Question  | Drug inquiry                                                                                                                    | Black/Pennington/Lockeed       |
| 3-16-20 | Rep. Zeldin                             | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Beyer                              | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Carter                             | Letter    | compounding pharmacies ability to make hand sanitizer and deal with shortages in drugs and OTC products during the COVID crisis | Black/Pennington               |
| 3-18-20 | HGSAC Minority                          | Questions | Medical product supply chain                                                                                                    | Hodnette                       |
| 3-18-20 | E&C                                     | Questions | Foreign Inspections – f/u from 3/18 briefing                                                                                    | Howard/Rosebraugh              |
| 3-19-20 | Senate HELP bipartisan & Sen. McConnell | Questions | Food & Feed Inspection and Food Waste Q&A                                                                                       | Colonus/Feingold/Lockeed       |
| 3-19-20 | National Governors Association          | Questions | Drug supply chain and diagnostics                                                                                               | Campbell                       |
| 3-19-20 | Sen. Pat Toomey                         | Question  | Remdesivir                                                                                                                      | Black/Pennington               |
| 3-19-20 | E&C                                     | Question  | Follow up questions from 3/19 E&C Briefing                                                                                      | Black/Pennington               |
| 3-19-20 | Congressional fellow                    | Question  | IND                                                                                                                             | Black/Pennington               |
| 3-20-20 | Sen. Cruz                               | Letter    | Drug Approvals                                                                                                                  | Black/Pennington               |

|         |                  |           |                               |                  |
|---------|------------------|-----------|-------------------------------|------------------|
| 3-20-20 | Rep. Eshoo       | Letter    | OTC Monograph /Hand Sanitizer | Black/Pennington |
| 3-23-20 | Multiple Members | Questions | Remdesivir and chloroquine    | Black/Pennington |

Thanks!

Caitlin

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/24/2020 4:01:12 PM  
**To:** OC OL Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a35f07a0600471ba92352df4d23029f-OC OL Staff]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]; OO-OFBA-Congressional-Government [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadd1dfbd5a648a186d6c00d81d6d0f3-OO-OFBA-Con]  
**Subject:** Daily Coronavirus Legislative Recap - 3/24/20

Good afternoon,

Here is today's daily recap of legislative activity (new inquiries and outstanding activity).

Please see the tracker for the most up-to-date information: <http://sharepoint.fda.gov/orgs/OC-OL/corona/Shared%20Documents/Open-Closed%20COVID-19%20Congressional%20Inquiries%202.25.20.xlsx> (all inquiries we received today are below).

**Today's meetings:**

- Phone call between Sen. Sullivan and Dr. Jeff Shuren
- Senate HELP Majority staff briefing on hand sanitizer guidance
- Phone call between Rep. Cleaver & Dr. Anand Shah
- House E&C Bipartisan staff briefing on Remdesivir

**NEW ITEMS**

- OL: Rep. DesJarlais inquiry re manufacturing essential medical supplies
- OL: Sen. Rand Paul inquiry on stem cells
- OL: Rep. Tlaib inquiry re Remdesivir
- OL: HELP Committee question re saline or IV solution supply
- OL: Sen. Capito inquiry re PPE
- OL: Rep. Luetkemeyer inquiry re drug development
- OL: Rep. Katko inquiry re hydroxychloroquine
- OL: Rep. Colin Peterson inquiry re ventilator shortage solution
- OL: Rep. Hudson inquiry re COVID Positive Test Protocols
- OL: Rep. Bera inquiry re COVID-19 Serology testing
- OL: Sen. Booker inquiry re masks
- OL: Oversight inquiry re hand sanitizer
- OCA: Rep. Aderholt inquiry re hospital masks
- IGA: Oregon state inquiry re masks

**IN PROGRESS**

| <u>Date</u> | <u>Office</u>        | <u>Type</u> | <u>Subject</u>                      | <u>OL Staff</u>                 |
|-------------|----------------------|-------------|-------------------------------------|---------------------------------|
| 2-24-20     | Sen. Josh Hawley     | Letter      | Medical supply chain                | Pennington/Lockeed/Paulos/Black |
| 2-26-20     | Sen. Tina Smith      | Letter      | Potential shortages                 | Pennington/Lockeed/Paulos/Black |
| 3-3-20      | Sens. Warren & Casey | Letter      | Fraudulent products                 | Pennington/Lockeed              |
| 3-4-20      | Rep. Crist           | Letter      | Coronavirus diagnostic availability | Pennington/Lockeed/Paulos       |
| 3-5-20      | Sen. Murray          | Letter      | COVID-19 testing                    | Pennington/Lockeed/Paulos       |

|         |                                         |           |                                                                                                                                 |                                |
|---------|-----------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 3-9-20  | Rep. Schakowsky, Doggett, & DeLauro     | Letter    | COVID-19 testing affordability                                                                                                  | Pennington/Lockeed/Paulos      |
| 3-9-20  | Rep. Meng +13                           | Letter    | COVID-19 testing                                                                                                                | Pennington/Lockeed/Paulos      |
| 3-9-20  | Sen. Blumenthal                         | Letter    | COVID-19 Warning Letters                                                                                                        | Pennington/Lockeed             |
| 3-10-20 | Rep. Higgins                            | Letter    | Testing of COVID-19 samples                                                                                                     | Pennington/Lockeed/Paulos/Rath |
| 3-10-20 | Rep. Gabbard                            | Letter    | Purchasing tests from South Korea and other testing questions                                                                   | Paulos/Lockeed                 |
| 3-10-20 | Sens. Warren & Murray                   | Letter    | Including pregnant and lactating women in COVID-19 vaccine clinical trials                                                      | Aguilar/Lockeed                |
| 3-11-20 | Reps. Rose & Reed                       | Letter    | Testing of COVID-19 Samples                                                                                                     | Paulos/Pennington/Lockeed      |
| 3-12-20 | Rep. Porter +80                         | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Thom Tillis                        | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-16-20 | Reps. Perlmutter & Veasey               | Letter    | Antivirals                                                                                                                      | Black/Pennington               |
| 3-16-20 | E&C Oversight                           | Question  | Nasal Swabs                                                                                                                     | Hodnette/Lockeed/Pennington    |
| 3-16-20 | Sen. Gardner                            | Letter    | EUAs/testing                                                                                                                    | Paulos/Pennington/Lockeed      |
| 3-16-20 | Sen. Blackburn                          | Question  | Drug inquiry                                                                                                                    | Black/Pennington/Lockeed       |
| 3-16-20 | Rep. Zeldin                             | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Beyer                              | Letter    | COVID-19 testing                                                                                                                | Paulos/Pennington/Lockeed      |
| 3-18-20 | Rep. Carter                             | Letter    | compounding pharmacies ability to make hand sanitizer and deal with shortages in drugs and OTC products during the COVID crisis | Black/Pennington               |
| 3-18-20 | HGSAC Minority                          | Questions | Medical product supply chain                                                                                                    | Hodnette                       |
| 3-18-20 | E&C                                     | Questions | Foreign Inspections – f/u from 3/18 briefing                                                                                    | Howard/Rosebraugh              |
| 3-19-20 | Senate HELP bipartisan & Sen. McConnell | Questions | Food & Feed Inspection and Food Waste Q&A                                                                                       | Colonus/Feingold/Lockeed       |
| 3-19-20 | National Governors Association          | Questions | Drug supply chain and diagnostics                                                                                               | Campbell                       |
| 3-19-20 | Sen. Pat Toomey                         | Question  | Remdesivir                                                                                                                      | Black/Pennington               |
| 3-19-20 | E&C                                     | Question  | Follow up questions from 3/19 E&C Briefing                                                                                      | Black/Pennington               |
| 3-19-20 | Congressional fellow                    | Question  | IND                                                                                                                             | Black/Pennington               |
| 3-20-20 | Sen. Cruz                               | Letter    | Drug Approvals                                                                                                                  | Black/Pennington               |
| 3-20-20 | Rep. Eshoo                              | Letter    | OTC Monograph /Hand Sanitizer                                                                                                   | Black/Pennington               |
| 3-23-20 | Multiple Members                        | Questions | Remdesivir and chloroquine                                                                                                      | Black/Pennington               |

|         |                             |           |                  |                  |
|---------|-----------------------------|-----------|------------------|------------------|
| 3-23-20 | Rep. Neguse                 | Letter    | Hand sanitizer   | Black/Pennington |
| 3-23-20 | Rep. Kind +<br>multi-member | Letter    | COVID-19 testing | Paulos           |
| 3-24-20 | Oversight<br>Committee      | Questions | PREDICT Question | Luebke/Hodnette  |

Thanks!

Caitlin

---

**From:** Manchester, Brittney [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD6CA86F5A3F43FFB295122F23A95770-BRITTNEY.MA]  
**Sent:** 3/31/2020 10:04:53 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue, March 31 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.03.31\_Final\_ToGoOut.docx

Hi—

OMA will be issuing this in the next 30 minutes. Thank you!

Thank you,  
Brittney

**Brittney Manchester**  
Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301-796-1026 | Cell: (b)(6)  
brittney.manchester@fda.hhs.gov



---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/3/2020 12:09:11 AM  
**To:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** Fwd: Coronavirus (COVID-19) Update: Daily Roundup April 2, 2020

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Date:** April 2, 2020 at 10:42:21 PM EDT  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup April 2, 2020

The FDA Office of Legislation would like to bring to your attention update on the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information.  
Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup April 2, 2020

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- Today, the FDA announced that it is revising recommendations in several guidances regarding blood donor eligibility. These changes are based on recently completed studies and epidemiological data, leading the FDA to conclude that the policies could be modified without compromising the safety of the blood supply. The changes being announced to three guidances (HIV, malaria and CJD/vCJD) are for immediate implementation, and are expected to remain in place after the COVID-19 pandemic ends, with any appropriate changes based on comments we receive and our experience implementing the guidances. Additionally, the FDA is publishing a fourth guidance providing notice of alternatives to certain requirements regarding blood donor eligibility for the duration of the COVID-19 pandemic. The guidances are available on FDA's web site.
- Food update to date: the FDA released a public service announcement on food safety and the food supply. Consumers should rest assured that the FDA is on the job and working tirelessly to keep the American food supply among the safest in the world. The agency still reports no widespread food shortages or food safety issues.



- Today, the FDA and Federal Trade Commission (FTC) issued warning letters to three companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. With these warning letters, the FDA is exercising its authority to protect consumers from companies selling unapproved products and making false or misleading claims during the COVID-19 pandemic.

- One of the companies warned, Gaia's Whole Healing Essentials LLC., sells unapproved and misbranded colloidal silver products with misleading claims the products can build immunity for the treatment or prevention of COVID-19.

- Another company warned, Homeomart Indibuy, offers homeopathic drug products for sale in the U.S. that are unapproved and misbranded with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19.

- The third company warned, Health Mastery Systems DBA Pure Plant Essentials, sells essential oils with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19.

- Diagnostics update to date:

- During the COVID-19 pandemic, the FDA has worked with more than 240 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.

- To date, 25 emergency use authorizations have been issued for diagnostic tests. Notably, the FDA issued an emergency use authorization, on April 1, 2020, to Cellex Inc.'s qSARS-CoV-2 IgG/IgM Rapid Test which is the first serology test to date to receive authorization to test for the presence of coronavirus antibodies. Cellex's labeling notes that test results from this serology test should not be used as the sole basis for diagnosis and can only aid in the diagnosis of patients in conjunction with a medical review of symptoms and results of other laboratory tests. Cellex's test is also limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform moderate and high complexity tests.

- The FDA has been notified that more than 125 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.

- The FDA also continues to keep its COVID-19 Diagnostics [FAQ](#) up to date.

- A new FDA Voices was issued: FDA Commissioned Corps Officers on the Front Line of COVID-19 Response. Almost 400 FDA Commissioned Corps officers have been deployed to aid in response to the pandemic. Among HHS agencies, the FDA is privileged to have the second highest number of Commissioned Corps officers serving in our ranks—more than 1,100 officers in total. This allows us to truly be on call 24/7 to protect America's food supply and essential medicines, and to ensure the safety of life-saving medical devices, vaccines and the blood supply during this pandemic. FDA's U.S. Public Health Service (USPHS) Commissioned Corps officers are highly-trained public health professionals who work nationally and internationally in careers such as medicine, veterinary sciences, dentistry, nursing, epidemiology and biomedical research to serve underserved and vulnerable communities.



---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/6/2020 9:47:47 AM  
**To:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** FW: Request from Senator Murkowski

FYI- in case we start getting calls from Alaska.....

---

**From:** Ramponi, Angela (Murkowski) <Angela\_Ramponi@murkowski.senate.gov>  
**Sent:** Monday, April 06, 2020 9:20 AM  
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>  
**Subject:** RE: Request from Senator Murkowski

Thanks Andrew,

This is helpful, I passed the IGA contacts along to the state. Senator Murkowski very much appreciated her call with Commissioner Hahn, thanks for taking the time to get that set up. If you have any follow-up info to provide please feel free to pass it along to me.

Thanks for everyone's work.

Angela

**Angela Ramponi**  
Office of U.S. Senator Lisa Murkowski  
522 Hart Senate Office Building  
(o) 202-224-3884 (c) (b)(6)

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Friday, April 3, 2020 3:08 PM  
**To:** Ramponi, Angela (Murkowski) <Angela\_Ramponi@murkowski.senate.gov>  
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>  
**Subject:** RE: Request from Senator Murkowski

Angela- Thanks for your time.

As I mentioned, our Intergovernmental Affairs Staff within the Office of the Commissioner is dedicated to working with local, state, and tribal governments. When the State has a question, it might consider reaching out to them at IGA@fda.hhs.gov. Karen Meister is the acting director of IGA and is copied here.

I also mentioned that the Government's response in this area is being coordinated by FEMA. You may want to wanted to consult <https://www.fema.gov/coronavirus/how-to-help> for information about how businesses can donate or sell medical supplies. It may be useful for the State's own understanding and to pass along to solicitors.

We in the Office of Legislation are also available to assist in any way we can. I am its Deputy Director and my boss, the Associate Commissioner for Legislation, is Karas Gross and she is also copied here. Lauren Paulos is running point for us

on medical devices, tests, and PPE, and Jen Black leads our work on drug development and shortages. Our general email box is [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov), but please feel free to contact any of us directly.

I will see about setting up a call and will get back to you asap.

---

**From:** Tantillo, Andrew  
**Sent:** Friday, April 3, 2020 11:28 AM  
**To:** Ramponi, Angela (Murkowski) <[Angela\\_Ramponi@murkowski.senate.gov](mailto:Angela_Ramponi@murkowski.senate.gov)>; Daimler-Nothdurft, Kristen (Murkowski) <[Kristen\\_Daimler-Nothdurft@murkowski.senate.gov](mailto:Kristen_Daimler-Nothdurft@murkowski.senate.gov)>; Boyle, Garrett (Murkowski) <[Garrett\\_Boyle@murkowski.senate.gov](mailto:Garrett_Boyle@murkowski.senate.gov)>; Dietderich, Anna (Murkowski) <[Anna\\_Dietderich@murkowski.senate.gov](mailto:Anna_Dietderich@murkowski.senate.gov)>  
**Cc:** Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>; Pennington, Caitlin <[Caitlin.Pennington@fda.hhs.gov](mailto:Caitlin.Pennington@fda.hhs.gov)>  
**Subject:** RE: Request from Senator Murkowski

Thank you – Angela, Anna, or Garrett, would you have a moment to touch base on this?

**(b)(6)** Thank you!

---

**From:** Ramponi, Angela (Murkowski) <[Angela\\_Ramponi@murkowski.senate.gov](mailto:Angela_Ramponi@murkowski.senate.gov)>  
**Sent:** Thursday, April 2, 2020 4:36 PM  
**To:** Daimler-Nothdurft, Kristen (Murkowski) <[Kristen\\_Daimler-Nothdurft@murkowski.senate.gov](mailto:Kristen_Daimler-Nothdurft@murkowski.senate.gov)>; Tantillo, Andrew <[Andrew.Tantillo@fda.hhs.gov](mailto:Andrew.Tantillo@fda.hhs.gov)>; Boyle, Garrett (Murkowski) <[Garrett\\_Boyle@murkowski.senate.gov](mailto:Garrett_Boyle@murkowski.senate.gov)>; Dietderich, Anna (Murkowski) <[Anna\\_Dietderich@murkowski.senate.gov](mailto:Anna_Dietderich@murkowski.senate.gov)>  
**Cc:** Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>; Pennington, Caitlin <[Caitlin.Pennington@fda.hhs.gov](mailto:Caitlin.Pennington@fda.hhs.gov)>  
**Subject:** RE: Request from Senator Murkowski

Hi Andrew,

Senator Murkowski would like to discuss FDA technical support for states. For example, assistance to health departments as they work to navigate numerous new product, technology, and manufacturing offers from industry.

Thanks,

Angela

**Angela Ramponi**  
Office of U.S. Senator Lisa Murkowski  
522 Hart Senate Office Building  
(o) 202-224-3884 (c) **(b)(6)**

---

**From:** Daimler-Nothdurft, Kristen (Murkowski) <[Kristen\\_Daimler-Nothdurft@murkowski.senate.gov](mailto:Kristen_Daimler-Nothdurft@murkowski.senate.gov)>  
**Sent:** Thursday, April 2, 2020 4:32 PM  
**To:** 'Tantillo, Andrew' <[Andrew.Tantillo@fda.hhs.gov](mailto:Andrew.Tantillo@fda.hhs.gov)>; Boyle, Garrett (Murkowski) <[Garrett\\_Boyle@murkowski.senate.gov](mailto:Garrett_Boyle@murkowski.senate.gov)>; Ramponi, Angela (Murkowski) <[Angela\\_Ramponi@murkowski.senate.gov](mailto:Angela_Ramponi@murkowski.senate.gov)>; Dietderich, Anna (Murkowski) <[Anna\\_Dietderich@murkowski.senate.gov](mailto:Anna_Dietderich@murkowski.senate.gov)>  
**Cc:** Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>; Pennington, Caitlin <[Caitlin.Pennington@fda.hhs.gov](mailto:Caitlin.Pennington@fda.hhs.gov)>  
**Subject:** RE: Request from Senator Murkowski

Angela can you please weigh in as I was not on the call with the Senator?

Kristen Daimler Nothdurft  
Executive Assistant/Scheduler  
Office of Senator Lisa Murkowski  
Hart Senate Office Building, room 522  
202-224-6665 phone  
202-224-4349 scheduling fax

Please note: No filming or recording of meetings is allowed without prior authorization. If you would like to bring a camera into the Senate office, please contact Senator Murkowski's Communications Director at [karina\\_borger@murkowski.senate.gov](mailto:karina_borger@murkowski.senate.gov). If you are planning to have more than 10 people in your group, or if anyone in the group has any accessibility needs/concerns, please let me know in advance so that I can be sure we have adequate space to accommodate your meeting. If you are planning to use her photo or bio for anything, please also contact our Press Department so that we can make sure we have the most up-to-date information for your event. Thank you!

---

**From:** Tantillo, Andrew <[Andrew.Tantillo@fda.hhs.gov](mailto:Andrew.Tantillo@fda.hhs.gov)>  
**Sent:** Thursday, April 2, 2020 4:29 PM  
**To:** Daimler-Nothdurft, Kristen (Murkowski) <[Kristen\\_Daimler-Nothdurft@murkowski.senate.gov](mailto:Kristen_Daimler-Nothdurft@murkowski.senate.gov)>; Boyle, Garrett (Murkowski) <[Garrett\\_Boyle@murkowski.senate.gov](mailto:Garrett_Boyle@murkowski.senate.gov)>; Ramponi, Angela (Murkowski) <[Angela\\_Ramponi@murkowski.senate.gov](mailto:Angela_Ramponi@murkowski.senate.gov)>; Dietderich, Anna (Murkowski) <[Anna\\_Dietderich@murkowski.senate.gov](mailto:Anna_Dietderich@murkowski.senate.gov)>  
**Cc:** Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>; Pennington, Caitlin <[Caitlin.Pennington@fda.hhs.gov](mailto:Caitlin.Pennington@fda.hhs.gov)>  
**Subject:** RE: Request from Senator Murkowski

Hi Kristen- Thank you for reaching out. Because COVID-19 is so wide-ranging, in order to facilitate a good conversation could you please share what aspect of COVID-19 Sen. Murkowski would like to discuss?

Thank you!

**Andrew Tantillo**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
O: 301-796-8919 M: (b)(6)  
[andrew.tantillo@fda.hhs.gov](mailto:andrew.tantillo@fda.hhs.gov)



---

**From:** Daimler-Nothdurft, Kristen (Murkowski) <>  
**Sent:** Thursday, April 2, 2020 3:22 PM  
**To:** Hageman, Natalie <[Natalie.Hageman@fda.hhs.gov](mailto:Natalie.Hageman@fda.hhs.gov)>  
**Cc:** Boyle, Garrett (Murkowski) <[Garrett\\_Boyle@murkowski.senate.gov](mailto:Garrett_Boyle@murkowski.senate.gov)>; Ramponi, Angela (Murkowski) <[Angela\\_Ramponi@murkowski.senate.gov](mailto:Angela_Ramponi@murkowski.senate.gov)>; Dietderich, Anna (Murkowski) <[Anna\\_Dietderich@murkowski.senate.gov](mailto:Anna_Dietderich@murkowski.senate.gov)>  
**Subject:** Request from Senator Murkowski

Hi Natalie, Senator Murkowski has asked me to see if she can arrange a call with the FDA Commissioner. Topic is COVID-19. Please let me know if such a call can be arranged?

Kristen Daimler Nothdurft  
Executive Assistant/Scheduler  
Office of Senator Lisa Murkowski  
Hart Senate Office Building, room 522

202-224-5341 direct number  
202-224-4349 scheduling fax

---

**From:** Gomez, Rachel A. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB9B744B3C3B4E3EA335C72BC527B8D8-RACHEL.GOME]  
**Sent:** 4/7/2020 8:01:54 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** RE: FDA Office of Legislation: Weekly Coronavirus Digest for the week of March 30, 2020

Does OL do a weekly outreach summary in place of each one separately during the week or is this in addition to? Just thinking that our regulars may not want to be overwhelmed with one more email. However, it does look nice

**Rachel Gomez 郭瑞秋**

*Intergovernmental Affairs (IGA) – Detailee*

Cell: (b)(6)

Assistant Country Director  
U.S. Embassy, P.R. of China  
Office of Global Policy and Strategy - Office of Global Operations  
U.S. Food and Drug Administration  
Rachel.Gomez@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 7, 2020 3:30 AM  
**To:** IGA Staff <IGASTaff@fda.hhs.gov>  
**Subject:** FW: FDA Office of Legislation: Weekly Coronavirus Digest for the week of March 30, 2020

Should we consider?

---

**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Saturday, April 04, 2020 1:02 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** FDA Office of Legislation: Weekly Coronavirus Digest for the week of March 30, 2020

## FDA Office of Legislation

---

### Weekly Coronavirus Digest for the week of March 30, 2020

Good Afternoon, the FDA Office of Legislation would like to bring to your attention the following actions the Agency took the week of March 30<sup>th</sup> in its ongoing response effort to the COVID-19 pandemic. If you have any questions on the below announcements, please reach out to us at [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov). Thank you!

A new FDA Voices was issued: FDA Commissioned Corps Officers on the Front Line of COVID-19 Response. Almost 400 FDA Commissioned Corps officers have been deployed to aid in response to the pandemic. Among HHS agencies, the FDA is privileged to have the second highest number of Commissioned Corps officers serving in our ranks—more than 1,100 officers in total. This allows us to truly be on call 24/7 to protect America’s food supply and essential medicines, and to ensure the safety of life-saving medical devices, vaccines and the blood supply during this pandemic. FDA’s U.S. Public Health Service (USPHS) Commissioned Corps officers are highly-trained public health professionals who work nationally and internationally in careers such as medicine, veterinary sciences, dentistry, nursing, epidemiology and biomedical research to serve underserved and vulnerable communities.

## Drugs & Biologics

- On March 28, 2020, the FDA issued an Emergency Use Authorization (EUA) to allow hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile(SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions. The SNS, managed by ASPR, will work with the Federal Emergency Management Agency (FEMA) to ship donated doses to states.
- FDA and FTC issued several warning letters this week:
  - Corona-cure.com, was warned for selling the product Coronavirus Infection Prevention Nasal Spray with misleading claims on its website that its product is safe and/or effective for the treatment or prevention of COVID-19.
  - Carahealth for selling its herbal products, including “Carahealth Immune,” with misleading claims of prevention and/or treatment of COVID-19. We are particularly concerned that unapproved drugs that claim to cure, treat, or prevent serious conditions may cause consumers to delay or stop appropriate medical treatment, leading to serious or life-threatening harm. There is currently no approved treatment or preventative measure for COVID-19. FDA and FTC are closely monitoring social media, the online marketplace, and incoming reports for fraudulent COVID-19 products on the market.
  - Halosense Inc., sells salt therapy products with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19.
  - Bioactive C60/FullerLifeC60 LLC, sells an unapproved and unauthorized product, “FullerLifeC60,” with misleading claims that it can build up immunity to help treat or prevent COVID-19 in people.
  - JRB Enterprise Group Inc. DBA Anti Aging Bed, offers colloidal silver products for sale in the U.S. with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19. With these warning letters, the FDA is exercising its authority to protect consumers from companies selling unapproved products and making false or misleading claims during the COVID-19 pandemic.
  - Gaia’s Whole Healing Essentials LLC., sells unapproved and misbranded colloidal silver products with misleading claims the products can build immunity for the treatment or prevention of COVID-19.
  - Homeomart Indibuy, offers homeopathic drug products for sale in the U.S. that are unapproved and misbranded with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19.
  - Health Mastery Systems DBA Pure Plant Essentials, sells essential oils with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19.
  - Neuro XPF, which sells cannabidiol (CBD) products in the U.S. with the misleading claim these products can mitigate, prevent, treat, diagnose, or cure COVID-19. The agency will continue to pursue those that place public health at risk.
- The FDA stood up a new program to expedite the development of potentially safe and effective life-saving treatments. The program, known as the Coronavirus Treatment Acceleration Program (CTAP), is using every tool at the agency’s disposal to bring new therapies to sick patients as quickly as possible, while at the same time supporting

research to further evaluate whether these medical countermeasures are safe and effective for treating patients infected with this novel virus.

- The FDA posted information regarding shortages of hydroxychloroquine and chloroquine to its drug shortages webpage due to a significant surge in demand. The agency is working with manufacturers to assess their supplies and is actively evaluating market demand for patients dependent on hydroxychloroquine and chloroquine for treatment of malaria, lupus and rheumatoid arthritis. All manufacturers are ramping up production, and the agency's webpage displays current availability. The FDA is working with manufacturers to ensure this can happen expeditiously and safely. The U.S. Department of Health and Human Services (HHS) has also accepted 30 million doses of hydroxychloroquine sulfate to the national stockpile and one million doses of chloroquine phosphate for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials. Use of the donated medications is expected to help ease supply pressures for the drugs. This is a fluctuating and dynamic situation and the FDA is actively engaged. The agency is updating its shortages lists regularly and continuing to communicate in real-time so that patients and healthcare providers have the most current information on product shortages in the U.S.
- The FDA announced that it is revising recommendations in several guidances regarding blood donor eligibility. These changes are based on recently completed studies and epidemiological data, leading the FDA to conclude that the policies could be modified without compromising the safety of the blood supply. The changes being announced to three guidances (HIV, malaria and CJD/vCJD) are for immediate implementation, and are expected to remain in place after the COVID-19 pandemic ends, with any appropriate changes based on comments we receive and our experience implementing the guidances. Additionally, the FDA is publishing a fourth guidance providing notice of alternatives to certain requirements regarding blood donor eligibility for the duration of the COVID-19 pandemic. The guidances are available on FDA's web site.
- The FDA announced that it is leading an effort, working collaboratively with government, industry and academic partners, to develop and implement a protocol that will provide convalescent plasma to patients in need across the country who may not have access to institutions with clinical trials in place. Convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19. This collaboration, involving BARDA, the American Red Cross and the Mayo Clinic, will allow for a simplified process for health care providers that will help ensure patient safety while allowing for the collection of needed information about product efficacy. The FDA anticipates that the effort will be able to move thousands of units of plasma to patients who need them in the coming weeks.

### **Food Safety and Veterinary Medicine**

- The FDA released a public service announcement on food safety and the food supply. Consumers should rest assured that the FDA is on the job and working tirelessly to keep the American food supply among the safest in the world. The agency still reports no widespread food shortages or food safety issues.
- The FDA issued a Constituent Update regarding guidance it released this week to provide temporary flexibility to chain restaurants and similar retail food establishments currently required to provide nutrition information, including calories, on menus and menu boards.
- To help minimize the potential impact of the COVID-19 pandemic on new animal drug development, the FDA issued guidance with recommendations for sponsors conducting ongoing studies to support new animal drug development. These recommendations are designed to help ensure the safety of animals, their owners, and study personnel, maintain compliance with good laboratory practice regulations and good clinical practices, and maintain the scientific integrity of the data during the COVID-19 pandemic. It also addresses questions regarding CVM's coordination with foreign regulatory authorities during the pandemic. The guidance aligns with similar recommendations for sponsors of human drugs, biologics and medical devices released in March.
- The FDA announced it will begin requesting that importers send records required under the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) rule electronically (or through other prompt

means) to the agency as it shifts to conducting these inspections remotely during the COVID-19 public health emergency.

- The FDA is further extending the comment period for the Laboratory Accreditation for Analyses of Foods proposed rule by an additional 90 days. The comment period had previously been extended until April 6, 2020. However due to the ongoing coronavirus public health emergency, the comment period will now close July 6, 2020.
- The FDA released a guidance document, Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency, to provide temporary flexibility regarding the packaging and labeling of shell eggs sold to consumers in retail food establishments.

## Devices

- On March 29, 2020, the FDA issued an immediately in effect guidance that outlines an enforcement policy to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers. The devices include those intended to make devices sterile, kill pathogens or other microorganisms and kill pathogens or microorganisms in the air. This policy reflects FDA's commitment to ease burdens on health care providers and facilities as they face COVID-19.
- The FDA amended the Emergency Use Authorization (EUA) for the Battelle Decontamination System for use in decontaminating compatible N95 respirators for reuse by health care personnel during the COVID-19 pandemic. This EUA is an important step forward in helping to reduce shortages in critical N95 respirators, by allowing for these important devices, when decontaminated, to be reused by medical professionals on the front lines of the COVID-19 pandemic.
- On March 30, 2020, the FDA issued an immediately in effect guidance to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this public health emergency.
- The FDA issued an updated guidance, "Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic," with an appendix adding questions and answers on this subject. We plan to update this appendix as new questions arise. This guidance is intended for industry, investigators and institutional review boards and was issued because we recognize that the COVID-19 pandemic may impact the conduct of clinical trials of medical products, including drugs, devices and biological products.
- FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data Now Available: In response to the COVID-19 pandemic, the FDA—in collaboration with the Centers for Disease Control and Prevention (CDC), the Biodefense and Emerging Infections Research Resources Repository (BEI Resources) and the Institute for Genome Sciences at the University of Maryland and the National Center for Biotechnology Information (NCBI)—developed quality-controlled, reference sequence data for the SARS-CoV-2 reference strain for the United States. Availability of traceable and quality-controlled data will help test developers and vaccine developers:
  - Expedite development of medical countermeasures.
  - Identify new or more stable targets for future tests.
  - Enable in silico confirmation of targets.
  - Support development of synthetic reference material.
  - Enable viral population/quasi species analysis.
- The FDA posted an FAQ answering whether respirators approved under standards used in other countries, such as KN95s, can be used in the US during the COVID-19 pandemic. The short answer is yes. In response to continued respirator shortages, the FDA also issued a new Emergency Use Authorization (EUA) for non-NIOSH-approved respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic. Lastly, the FDA revised an immediately in effect guidance to help expand



the availability of general use face masks for the general public and respirators (including N95 and KN95) for health care professionals during this pandemic.

- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 240 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, 28 emergency use authorizations have been issued for diagnostic tests.
  - The FDA has been notified that more than 125 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics [FAQ](#) up to date.

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/7/2020 10:14:44 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** RE: For JIC Review: Application Discussion Response and Blast Email - please clear by 4 pm today

I think so. We can just wait til it gets cleared for OL

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, April 07, 2020 10:05 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; IGA Staff <IGASTaff@fda.hhs.gov>  
**Subject:** RE: For JIC Review: Application Discussion Response and Blast Email - please clear by 4 pm today

Looks good to me, and I think it would be appreciated (b)(5)  
(b)(5)

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Christopher.Campbell@fda.hhs.gov



---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 7, 2020 9:57 AM  
**To:** IGA Staff <IGASTaff@fda.hhs.gov>  
**Subject:** FW: For JIC Review: Application Discussion Response and Blast Email - please clear by 4 pm today

Check this out. OL sending an update to congressional staffers re: resources, etc.

(b)(5)

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Tuesday, April 07, 2020 9:10 AM  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFAIMGJIC@fda.hhs.gov>  
**Subject:** For JIC Review: Application Discussion Response and Blast Email - please clear by 4 pm today

Good morning all,

Please review the following email we would like to send to Congressional staffers regarding resources/contacts for them at the Agency: <http://sharepoint.fda.gov/orgs/OC-OL/Cross%20Cutting/Proactive%20COVID%20Outreach%203.23.20.docx>.

Thank you!

*Caitlin*

**Caitlin M. Pennington, MSM**

Special Assistant

Office of Legislation

Caitlin.Pennington@fda.hhs.gov

Direct line: 301-796-7064



---

**From:** Sauve, Michelle (ACF) [Michelle.Sauve@acf.hhs.gov]  
**Sent:** 4/7/2020 11:10:16 AM  
**To:** Allender, Michelle (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02266ac4d07547d7bb807afd2218a053-HHS-MAllend]; Buchanan, Sharunda D (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71624b2c73ac41c3b69e74185bb4286b-HHS-sdb4-cd]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08f0f7ae915401d4-Chrisopher]; Clelland, Carmen C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94ccc58cba643a8ab8eb5c1eb77eae3-HHS-yur3-cd]; Dave Wilson [dave.wilson2@nih.gov]; Ecoffey, Stacey (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d7cecb5a4d420caca5a23954f0712e-HHS-stacey.]; Elwood, Will [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Golub, Melinda V (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4582116ed4f4d12ae15084018b13fdc-HHS-Melinda]; Karol, Susan (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=046469476d394983875fd594f53ca71e-HHS-Susan.K]; Keane, Edmund D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9505c7b35db14d399d22ee2403278395-HHS-edmund.]; Killsback, Damion (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=095f2fbab2ac4f46a9d2352dc95927a3-HHS-Damion.]; LaCounte, Cynthia (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb8934b32ff425f81ee7eae852989a2-HHS-Cynthia]; Martin, Elijah (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=228568c0985f4c778e558630a649302b-HHS-EMartin]; Marx, Kitty (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d94f8c77ef2c4ff8b64fd94db4a97756-HHS-kitty.m]; Petrova, Angela (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16d716e13dec4c35971676aa04e58b4b-HHS-Angela.]; Pierce, Julia (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=179763bd077c449db45a733a90bf2933-HHS-Julia.P]; Scott, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba72cc5cf1c343028a4a1d716cd7d784-HHS-Katheri]; Smith, Benjamin (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a614c38c7a4745419145d1d32b56978c-HHS-Benjami]; Thundercloud, Alec (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf81d1fef104433d82fea1beefabae2f-HHS-Alec.Th]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Wade, Jennifer M (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf4329dcc6b84bac9eeab8afa843cef1-HHS-Jennife]; Wassink, Bradley (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=859953592a4745fbb8fd7b12ad370280-HHS-Bradley]  
**CC:** Hovland, Jean (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=609b94881741492cb0c4187de65bfae9-HHS-Jean.Ho]  
**Subject:** FW: ACF Native American COVID-19 Resources  
**Attachments:** ACF NA COVID-19 Resources FINAL 040620.docx

Update specific for Tribes/Native American Grantees

Good Morning. I am pleased to announce the Administration for Children and Families (ACF) Native American Coronavirus Disease 2019 (COVID-19) Resources document. The ACF is deeply concerned for the health and safety of those involved in ACF programs and the effect on human services in areas affected by the

COVID-19. ACF supports critical programs that are important for tribes and Native American communities as they respond to this public health emergency. ACF has taken proactive measures to help support programs within Native American communities. These measures include grant modification and flexibility for current grantees to ensure continued support of their projects and staff. Further information on these resources can be found on the Administration for Native Americans (ANA) website at <https://www.acf.hhs.gov/ana/news/acf-native-american-covid-19-resources>. ANA will continue to post updates on ACF COVID-19 resources and information on our website. Please sign up on ANA's listserv to receive email notifications and follow us on the ANA Facebook and Twitter accounts. Thank you.

Warm Regards,

Jeannie Hovland  
Deputy Assistant Secretary for Native American Affairs  
Commissioner | Administration for Native Americans  
HHS/ACF  
Mary E. Switzer Building  
330 C Street, SW  
Washington, DC 20024  
@ANA ACFgov



---

**From:** Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]  
**Sent:** 4/9/2020 6:33:35 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue April 9 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.04.09\_Final ToGoOut.docx

Hi –

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Molly

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/13/2020 2:21:32 AM  
**To:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** FW: Reactive TPs 4.10.20  
**Attachments:** Reactive TPs 4.10.20.docx

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

**Sent:** Friday, April 10, 2020 3:13 PM

**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>

**Cc:** Adleberg, Jill <Jill.Adleberg@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Burns, Corey <Corey.Burns@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Feingold, Daniel <Daniel.Feingold@fda.hhs.gov>; George, Bryan <Bryan.George@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Lexer, Susan <Susan.LexerSmith@fda.hhs.gov>; Lockheed, Matthew <Matthew.Lockheed@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Rosebraugh, Sydney <Sydney.Rosebraugh@fda.hhs.gov>

**Subject:** Reactive TPs 4.10.20

Please find attached the Office of Legislation's Reactive Talking Points document, updated through today. We did some pruning, so if you see something missing that you found helpful please let us know.

Thank you and have a restful weekend.

**Andrew Tantillo**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
301-796-8919 M: (b)(6)  
andrew.tantillo@fda.hhs.gov



---

**From:** Brown, Akeisha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=802C3F43976C4EAE88F559C26CB51BE5-AKEISHA.BRO]  
**Sent:** 4/13/2020 2:46:41 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** RE: Request for Input for 13 April Update on FDA 2019-nCoV SITREP

Hi Caitlin,

Below are IGA's inquiries for 4.10.20:

Malcolm Broussard, Louisiana Board of Pharmacy, asking whether FDA "would allow pharmacies to compound [hand sanitizer] for over-the-counter sale. Or is it still that pharmacies may only compound such products pursuant to patient-specific prescriptions?"

Office of Governor Henry McMaster State of South Carolina is requesting assistance from FDA regarding a shipment for the Medical University of South Carolina that is being held up at the FDA Memphis office.

**Akeisha Brown**

*Congressional Affairs Assistant*

Office of Legislation

U.S. Food and Drug Administration

Office: (301) 796-8900

Cell: (b)(6)

legislation@fda.hhs.gov



---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Monday, April 13, 2020 10:14 AM  
**To:** Price, William <William.Price@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Request for Input for 13 April Update on FDA 2019-nCoV SITREP

Hi Taylor and Akeisha,

Can you please provide me with OCA & IGA updates by 2:45 pm today?

Thanks!

Caitlin

---

**From:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>  
**Sent:** Monday, April 13, 2020 10:09 AM  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi



<Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Gindes, Melinda F <Melinda.Gindes@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Newkirk, Ryan <Ryan.Newkirk@fda.hhs.gov>; Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Montgomery, Alfred <Alfred.Montgomery@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>

**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>

**Subject:** Request for Input for 13 April Update on FDA 2019-nCoV SITREP

Hi All,

Attached is the draft 13 April SITREP on the FDA response to the 2019-nCoV outbreak.

As always, **provide any new updates, or let me know if you do not have new updates, by 3:30 PM.**

Please highlight any info that should not be shared outside of FDA in red.

Thank you for your continued assistance with this effort. Let me know if you have any questions or concerns.

Best,  
Greg

**Gregory Measer, JD**

*Regulatory Counsel*

Office of Counterterrorism and Emerging Threats  
Office of the Chief Scientist, Office of the Commissioner  
U.S. Food and Drug Administration  
202-774-4146 / [Gregory.Measer@fda.hhs.gov](mailto:Gregory.Measer@fda.hhs.gov)



---

**From:** Brown, Akeisha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=802C3F43976C4EAE88F559C26CB51BE5-AKEISHA.BRO]  
**Sent:** 4/16/2020 11:19:55 AM  
**To:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Representative Allen letter  
**Attachments:** Erick Allen-Sterigenics Response

Good Morning,

I sent the attached letter to CDRH ExecSec email box for signature, but I still have not received an update or response. Is there a direct contact at CDRH ExecSec that I should mail the letter to, or should I just wait for a response?

**Akeisha Brown**

*Congressional Affairs Assistant*

**Office of Legislation**

**U.S. Food and Drug Administration**

Office: (301) 796-8900

Cell: (b)(6)

legislation@fda.hhs.gov



---

**From:** Brown, Akeisha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=802C3F43976C4EAE88F559C26CB51BE5-AKEISHA.BRO]  
**Sent:** 4/16/2020 11:39:26 AM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**CC:** IGA Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b65d5118b84c739f63255db1142d43-IGA Staff]  
**Subject:** Rep. Allen-Sterigenics Letter  
**Attachments:** EtO Erick Allen Response.CDRH Cleared - 4-13-2020 - OPLIA edits - OCC-UA.docx; Erick Allen-Sterigenics Response

Good Morning,

I sent the attached letter to the CDRH ExecSec email yesterday afternoon. I'm sending you a copy for action in case the original email has not been received. Please let me know if there is a contact person at CDRH ExecSec that should receive all final type letters.

Regards,

**Akeisha Brown**

*Congressional Affairs Assistant*

**Office of Legislation**

**U.S. Food and Drug Administration**

Office: (301) 796-8900

Cell: (b)(6)

legislation@fda.hhs.gov



---

**From:** Kahn, Jeremy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B98D36D2C1F4AE795140B68DE7B37F7-JEREMY.KAHN]  
**Sent:** 4/27/2020 8:56:18 AM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]  
**Subject:** Preparing to Issue: Coronavirus Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns  
**Attachments:** 04102020- FDA Statement- Sanitizers\_ FINAL FINAL nometa.docx

Good morning-

OMA is preparing to issue the following: Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns

Thank you,  
--Jeremy

**Jeremy Kahn**  
*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 301-796-8671  
[jeremy.kahn@fda.hhs.gov](mailto:jeremy.kahn@fda.hhs.gov)



---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 4/27/2020 9:40:29 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns

Good morning –

**FDA's Intergovernmental Affairs (IGA) team would like to bring your attention to the following update on the Agency's efforts to ensure the availability of alcohol-based sanitizer to help meet the demand for hand sanitizer during the COVID-19 pandemic.**

We hope this information is helpful to you.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Best,

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)



## **Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Addresses Safety Concerns**

*Agency Additionally Warns Consumers about Hand Sanitizer Sold with Fraudulent Claims*

Today, the U.S. Food and Drug Administration provided an update on its efforts to ensure the availability of alcohol-based sanitizer to help meet the demand for hand sanitizer during the COVID-19 pandemic. As a result of the agency's significant flexibility, more than 1,500 additional manufacturers have registered with the agency to produce hand sanitizer. At the same time, the agency is addressing safety concerns related to products being sold that are not in line with the FDA's policy and others being marketed with unproven claims.

"We appreciate industry's willingness to help supply alcohol-based hand sanitizer to the market to meet the increasing demand for these products and are grateful for their efforts," said FDA Commissioner Stephen M. Hahn, M.D. "With this increased supply comes our continued mission to ensure safety of these products. It is important that hand sanitizer be manufactured in a way that makes them unpalatable to people, especially young children, and that they are appropriately labeled to discourage accidental or intentional ingestion. Additionally, hand sanitizers are not proven to treat COVID-19, and like other products meant for external use, are not for ingestion, inhalation, or intravenous use."

Following the FDA's guidance aimed at increasing availability of alcohol-based hand sanitizers, the agency has received feedback and questions over the past few weeks from industry and congressional members,

particularly regarding the need to use denatured alcohol for these products. Adding these denaturants to the alcohol renders the product more bitter and less appealing to ingest, particularly for young children. While the agency understands the economic and business reasons behind foregoing this step in the manufacturing process, such an approach undermines the agency's mission of helping to ensure the safety of FDA-regulated products for consumer use, which is the FDA's top priority. This approach is consistent with the FDA's policies prior to the COVID-19 pandemic on including denatured alcohol in hand sanitizer and is even more important now as more consumers rely on its use as a mitigation tool against the deadly virus.

To illustrate the importance of using denatured alcohol and, according to an FDA analysis of data provided by the U.S. Centers for Disease Control and Prevention and the American Association of Poison Control Centers surveillance team, calls to the National Poison Data System last month related to hand sanitizer increased by 79% compared to March 2019. The majority of these calls were for unintentional exposures in children 5 years of age and younger. Every year, there are hundreds of calls to poison control centers regarding exposure to hand sanitizer, many of which result in adverse events, including death. Unfortunately, ingestion of only a small amount of hand sanitizer may be potentially lethal in a young child.

This month, the agency received an adverse event report of a 13-year-old child drinking hand sanitizer packaged in a liquor bottle from a distiller. The sanitizer was not denatured and was reported to taste like normal drinking alcohol. To protect consumers, especially children, it is important to make hand sanitizer unpalatable.

The FDA also found that the product ingested by the 13-year-old child was not consistent with the labeling component of the agency's temporary policy— underscoring the importance that these products include a Drug Facts Label, warnings to keep the product out of reach of children, information to get medical help or call a poison control center right away if swallowed and to supervise use in children under 6 years of age to prevent accidental swallowing. These safety measures apply regardless of where the product is intended to be used, as it can easily be distributed beyond the original intended setting.

The FDA is also concerned about hand sanitizer products being sold by some manufacturers during the COVID-19 pandemic with unproven claims. Last week, the agency issued its first warning letter for a hand sanitizer product marketed with unproven COVID-19-related claims, in violation of federal law. The letter was issued to Prefense LLC for selling their product with misleading claims, for example, "Prefense...protects you from germs with just one application per day! It's like wearing an invisible glove." The company's webpage also states that Prefense can, "protect you from pathogens up to 24 hours or for 10 hand washes." The FDA is not aware of any evidence that hand sanitizer products can protect consumers for 24 hours or after multiple hand-washings. These types of claims may put consumers at risk by leading to a false sense of security and resulting in infrequent hand washing or hand sanitizing. The agency urges consumers to be vigilant of products sold with misleading, unproven claims, by following our updates on our [website](#).

The FDA remains committed to working with manufacturers, compounders, state boards of pharmacy and the public to increase the safe supply of alcohol-based hand sanitizer available to Americans, as well as continuing to take appropriate action against manufacturers making unproven claims.

Consumers, manufacturers or distributors who have questions for the FDA regarding hand sanitizers should email [COVID-19-Hand-Sanitizers@fda.hhs.gov](mailto:COVID-19-Hand-Sanitizers@fda.hhs.gov)

**Additional Resources:**

- [FDA: Novel coronavirus \(COVID-19\)](#)

---

**From:** Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]  
**Sent:** 4/28/2020 5:06:16 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue April 28 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.4.28\_Final ToGoOut.docx

Hi –

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Molly

---

**From:** Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]  
**Sent:** 4/29/2020 6:31:57 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue April 29 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.4.29\_Final ToGoOut.docx

Hi –

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Molly



---

**From:** Wiley, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DB729BC60C0140FD968242E8C817D38C-WILEYE]  
**Sent:** 5/4/2020 11:13:37 PM  
**To:** Wiley, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db729bc60c0140fd968242e8c817d38c-WILEYE]; O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILLJ]; Rovin, Lisa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ab536b0812946e782a5635c5e3e37da-Lisa.Rovin]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bd04f42f0afb9dd6abf39793a-Daniel.Hatt]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tropea, Josephine T. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7448bd63bffe4ea2b20b87816b18faaa-jts]; Sobel, Isabel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4939ca1a32e467986d4d6d143c8caba6-ISobel]; Jackson, Valerie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbeac5d29ba247128b43177b06d5d847-VJackson]; Flamm, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72d91495273741e0ae2b7c6cf01b9e3c-EFLAMM]; Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Cardin, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c1d42251310b4a328f2a677de8b101b1-Megan.Cardin]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Shapley, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dd55e42834c47d583e1fc7a756a0a06-SSHAPLEY]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Dooren, Jennifer

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95dfa06e432-Jennifer.Do]; Lenihan, Keagan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Copeland, Jakea  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Cristinzio, Dayle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Rabin, Tara G.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Stark, Angela  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Hinton, Denise  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Nguyen, Michael A.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Davies, Kathleen  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81e08967c7448d6a9327938015e9f1f-DaviesK]; Helms Williams, Emily  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Tobias, Lindsay  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zembower, Jenna  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Elwood, Will  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be0131ff86e94523a3574eb666e9fa68-William.Elw]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Tarver, Darian B.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Dupont, Jarilyn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Meyer, Raymond  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09b2e97a15624941aef7b5b4ae5c12de-MEYERR]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hoffman, Allison  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; George, Michelle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f376703c076a4f0eb4662b160ea0e530-Michelle.Ge]

**Subject:** Internal Strategic Planning (ISP) Meeting \*Materials added  
**Attachments:** WAR FINAL 4-30-20.pdf; FDA Communications Forecast\_5.15.20.docx; ISP Agenda 5-5-20 Final.docx  
**Location:** Call In: 877-465-7975/Access Code: (b)(6)

**Start:** 5/5/2020 9:30:00 AM  
**End:** 5/5/2020 10:15:00 AM  
**Show Time As:** Tentative

**Recurrence:** Weekly  
every Tuesday from 9:30 AM to 10:15 AM

---

**Required** Wiley, Elizabeth; O'Neill, Jeff; Rovin, Lisa; Cohen, Kenneth; Rebello, Heidi; Tyler, James; Alexander, Nicholas;  
**Attendees:** McBride, Maren; Beardsley, Sara; Hattis, Daniel; Klimczak, Katherine  
**Optional** Rom, Colin; Tropea, Josephine T.; Sobel, Isabel; Jackson, Valerie; Flamm, Eric; Helmanis, Lisa M; Tantillo, Andrew;  
**Attendees:** Schiller, Lowell; McWilliams, Carly; Cardin, Megan; Peddicord, Sarah; Shapley, Stephanie; Roth, Lauren; Sheehy, Janice; Lutter, Randall; Anderson, Erika; Dooren, Jennifer; Lenihan, Keagan; Copeland, Jakea; Cristinzio, Dayle; Rabin, Tara G.; Stark, Angela; Hinton, Denise; Nguyen, Michael A.; Davies, Kathleen; Helms Williams, Emily; Flahive, James; Tobias, Lindsay; Zembower, Jenna; Elwood, Will; Franklin, Joseph; Tarver, Darian B.; Dupont, Jarilyn; Felberbaum, Michael; Meyer, Raymond; Walsh, Sandy; Hoffman, Allison; Lynch, Sarah; George, Michelle

\*Materials added for 5/5/2020:



ISP Agenda 5-5-20  
Final.docx



FDA  
Communications...



WAR FINAL  
4-30-20.pdf

**Internal Strategic Planning (ISP) Meeting** is held weekly on Tuesday's at 9:30 am.

**Location:** Dial In Only

**Directions using a WebEx number:**

1. Toll Free: **1-877-465-7975** or 1-210-795-0506 US Toll
2. Enter Access Code  press # (No pin required for attendees)

**Please do not forward this invite.**

If you have questions, please contact Elizabeth (Betsy) Wiley, 301-796-3479.

---

**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 5/11/2020 7:15:27 PM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]  
**Subject:** PREPARING TO ISSUE: Press Release, "Coronavirus (COVID-19) Update: FDA Takes New Actions to Accelerate Development of Novel Prevention, Treatment Options for COVID-19"  
**Attachments:** FINAL\_PR\_COVID Therapy Guidances 05112020-FOR POSTING.docx

Hello,

The attached press release entitled, "Coronavirus (COVID-19) Update: FDA Takes New Actions to Accelerate Development of Novel Prevention, Treatment Options for COVID-19," will issue shortly on FDA's website.

Please do not distribute until the press release is live on our website here: <https://www.fda.gov/news-events/fda-newsroom/press-announcements>.

Thank you!

Michael

**Michael Felberbaum**  
*Senior Advisor*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-9548 / Cell: 202-906-0229  
[michael.felberbaum@fda.hhs.gov](mailto:michael.felberbaum@fda.hhs.gov)



---

**From:** Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]  
**Sent:** 5/14/2020 9:09:05 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue May 14 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.05.14\_FINAL ToGoOut.docx

Hi –

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Molly

---

**From:** Herring, Kenneth (Lee) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=24DA18002BF64AE788C452B94F4BB12A-KENNETH.HER]  
**Sent:** 6/2/2020 6:59:40 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue JUNE 2 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.06.02\_FINAL ToGoOut.docx

Good evening,

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,

**K. Lee Herring**

*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Cell: (b)(6)  
lee.herring@fda.hhs.gov

---

**From:** Saghafi, Michelle [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C64D4CC782A94188AE15E0549DFFEFCA-MICHELLE.SA]  
**Sent:** 6/5/2020 3:45:59 PM  
**To:** OC-Executive Secretariat-Policy Analysts [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13f9e7ff68a04df59c53698f65bac2f6-OC-Executiv]; OEA External Communications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dc23bbf65b0459eb8661d53c2fcd341-OEA Externa]  
**Subject:** FDA Communications Forecast (Mon., June 8 - Fri., June 19)  
**Attachments:** FDA Communications Forecast\_6.19.20.docx

Good Afternoon,

Please find attached the FDA Communications Forecast for the next two weeks (Mon., June 8 - Fri., June 19).

As a reminder, it contains commercial confidential information.

Thanks,

Michelle

**Michelle A. Saghafi, MBA**  
*Public Affairs Specialist*

Office of Editorial and Creative Services  
Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-8628 / Cell: (b)(6)

michelle.saghafi@fda.hhs.gov



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/13/2020 1:58:46 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: Update on Undiagnosed Pneumonia - China - 13 JAN

FYI. HHS/FDA is monitoring this situation along with our USG and WHO public health colleagues. FDA SMEs will be joining a technical call with the WHO tomorrow, along with other HHS and DoD colleagues, to touch base on potential collaborations on this front. Thanks.

Internal confidential

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Monday, January 13, 2020 1:12 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Cc:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>  
**Subject:** Update on Undiagnosed Pneumonia - China - 13 JAN

Hi – wanted to provide u w/updates of what happened over the weekend – m

**Overview:**

- As of 12 JAN, WHO reports that there are 41 confirmed cases and one death:
  - 41 cases with novel coronavirus infection have been preliminarily diagnosed in Wuhan City.
  - Of the 41 cases reported, seven are severely ill.
  - The 1 death reported was in a patient with other underlying health conditions.
  - Six patients have been discharged from hospital.
  - Symptom onset of the 41 confirmed nCoV cases ranges from 8 December 2019 to 2 January 2020.
  - No additional cases have been detected since 3 January 2020.
  - According to the preliminary epidemiological investigation, most cases worked at or were handlers and frequent visitors to the Huanan Seafood Wholesale Market.
  - The Chinese government reports that there is no clear evidence that the virus passes easily from person to person.
  - A total of 763 close contacts including healthcare workers, have been identified and followed up and no additional cases of infection with the novel coronavirus have been identified
- On 13 JAN, WHO reported confirmation of the novel coronavirus in a person in Thailand who was a traveler from Wuhan, China, and was identified by Thai officials on 8 January, and hospitalized that day. The person is recovering from the illness according to Thai officials.
- The Shanghai Public Health Clinical Center & School of Public Health, in collaboration with the Central Hospital of Wuhan, Huazhong University of Science and Technology, the Wuhan Center for Disease Control and Prevention, the National Institute for Communicable Disease Control and Prevention, Chinese Center for Disease Control, and the University of Sydney, Sydney, Australia released a coronavirus genome from a case of a respiratory disease from the Wuhan outbreak. The sequence has also been deposited on GenBank (accession [MN908947](#)).
- CIDRAP reported that Vineet Menachery, PhD, with the University of Texas Medical Branch (UTMB) said on Twitter that nCoV appears to be a group 2B coronavirus, which puts it in the same family as the SARS (severe acute respiratory syndrome) virus and that Andrew Rambaut, PhD, administrator of Virological.org and professor of molecular evolution at the University of Edinburgh, said on Twitter that nCoV is 89% similar to SARS-related bat coronavirus in the Sarbecovirus group of betacoronaviruses.



**WHO Activities:**

- WHO released Technical guidance for novel coronavirus

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/19/2020 8:39:35 PM  
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: Wuhan nCoV outbreak quadruples, spreads within China

Thanks, Peter. Plus Dr. Hahn for his awareness as I mentioned to him on a Friday afternoon that the team is being vigilant on this front.

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 19, 2020 at 6:01:23 PM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Wuhan nCoV outbreak quadruples, spreads within China

Dear Anna,

I remember we spoke on Friday and you asked about whether this was something of concern. I mentioned that it depended on what happened over the next week. Well, now this is indeed something of concern, especially since some of these cases could have been from person to person transmission. I suspect that the number of meetings on this topic will increase notably this week.

We will monitor very closely.

Best Regards,  
Peter

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Sunday, January 19, 2020 5:02 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Wuhan nCoV outbreak quadruples, spreads within China

<http://www.cidrap.umn.edu/news-perspective/2020/01/wuhan-ncov-outbreak-quadruples-spreads-within-china>

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/20/2020 5:04:08 PM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]  
**Subject:** Re: Emergency Committee meeting on the n2019-nCoV under the International Health Regulations - 22 January 2020.

Thanks, Anna

---

**From:** Anna Abram <Anna.Abram@fda.hhs.gov>  
**Date:** Monday, January 20, 2020 at 4:59 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Mark Abdo <Mark.Abdo@fda.hhs.gov>  
**Subject:** FW: Emergency Committee meeting on the n2019-nCoV under the International Health Regulations - 22 January 2020.

FYI. We will continue to closely monitor.

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Monday, January 20, 2020 4:59 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Emergency Committee meeting on the n2019-nCoV under the International Health Regulations - 22 January 2020.

WHO Director-General [@DrTedros](#) will convene an Emergency Committee on the novel [#coronavirus](#) (2019-nCoV) under the International Health Regulations. The Committee will meet on Wednesday, 22 January 2020.

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/20/2020 7:04:40 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Fwd: Human-to-human coronavirus transmission confirmed in China

See below. Reports of confirmed human-to-human transmission. Will keep you posted.

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 20, 2020 at 6:00:51 PM EST  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** RE: Human-to-human coronavirus transmission confirmed in China

Dear Michael,

Thanks so much for forwarding. That seems to answer that. Hold onto your hat, as I suspect that we may find out that there are many more cases....

Best Regards,  
Peter

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Monday, January 20, 2020 5:58 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Human-to-human coronavirus transmission confirmed in China

<https://www.nbcnews.com/news/world/human-human-transmission-confirmed-china-coronavirus-n1118866>.

---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 1/21/2020 9:23:04 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Please Join SH: "AMA reoccurring meeting with CDC Director, Dr. Robert Redfield- Coronavirus"  
**Location:** Commissioner's Office (WO1/2217)  
**Start:** 1/21/2020 11:15:00 AM  
**End:** 1/21/2020 12:15:00 PM  
**Show Time As:** Busy

**Required Attendees:** Abram, Anna; Lenihan, Keagan

The Commissioner will be dialing in from his office, please join in person.

*"Jan 21st - Dr. Redfield will be here in person for this meeting.*

*Bi-weekly meeting with CDC for updates*

*Lead: Danielle Steele*

*TOPIC: Wuhan update*

*Topic: Dr. Redfield to brief the Secretary on the CDC PFAS tox profile*

*"The proposed agendas for these meetings need to be shared with your Senior Advisor 72 hours in advance of the scheduled interaction. The senior advisor will share it with the Deputy Chief of Staff for Policy and both will confirm or suggest changes. When you submit the proposed agenda, please note whether or not there is any expectation for a decision. As a matter of course, these are NOT decision meetings, but we will entertain exceptions for especially time-sensitive issues. Please also note that materials for these meetings are to be submitted for the Secretary's book by 500pm two working days prior to the interaction (e.g., for a Monday meeting it would be due the prior Thursday at 500pm). Depending on the topics to be discussed, we will invite other relevant parties to attend. Thank you for your cooperation. All of this is to insure the interactions are optimally productive for all involved"*

---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 1/21/2020 9:23:04 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Please Join SH: "AMA reoccurring meeting with CDC Director, Dr. Robert Redfield- Coronavirus"  
**Location:** Commissioner's Office (WO1/21217)  
**Start:** 1/21/2020 11:15:00 AM  
**End:** 1/21/2020 12:15:00 PM  
**Show Time As:** Busy

**Required Attendees:** Abram, Anna; Lenihan, Keagan

The Commissioner will be dialing in from his office, please join in person.

*"Jan 21st - Dr. Redfield will be here in person for this meeting.*

*Bi-weekly meeting with CDC for updates*

*Lead: Danielle Steele*

*TOPIC: Wuhan update*

*Topic: Dr. Redfield to brief the Secretary on the CDC PFAS tox profile*

*"The proposed agendas for these meetings need to be shared with your Senior Advisor 72 hours in advance of the scheduled interaction. The senior advisor will share it with the Deputy Chief of Staff for Policy and both will confirm or suggest changes. When you submit the proposed agenda, please note whether or not there is any expectation for a decision. As a matter of course, these are NOT decision meetings, but we will entertain exceptions for especially time-sensitive issues. Please also note that materials for these meetings are to be submitted for the Secretary's book by 500pm two working days prior to the interaction (e.g., for a Monday meeting it would be due the prior Thursday at 500pm). Depending on the topics to be discussed, we will invite other relevant parties to attend. Thank you for your cooperation. All of this is to insure the interactions are optimally productive for all involved"*

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/21/2020 9:27:30 AM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Human-to-human coronavirus transmission confirmed in China

Thanks

---

**From:** Anna Abram <Anna.Abram@fda.hhs.gov>  
**Date:** Monday, January 20, 2020 at 7:04 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: Human-to-human coronavirus transmission confirmed in China

See below. Reports of confirmed human-to-human transmission. Will keep you posted.

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 20, 2020 at 6:00:51 PM EST  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** RE: Human-to-human coronavirus transmission confirmed in China

Dear Michael,

Thanks so much for forwarding. That seems to answer that. Hold onto your hat, as I suspect that we may find out that there are many more cases....

Best Regards,  
Peter

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Monday, January 20, 2020 5:58 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Human-to-human coronavirus transmission confirmed in China

<https://www.nbcnews.com/news/world/human-human-transmission-confirmed-china-coronavirus-n1118866>

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/21/2020 1:42:32 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: CDC expected to announce first US case of Wuhan coronavirus

FYI

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Tuesday, January 21, 2020 1:34 PM  
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** CDC expected to announce first US case of Wuhan coronavirus

<https://www.google.com/amp/s/amp.cnn.com/cnn/2020/01/21/health/wuhan-coronavirus-first-us-case-cdc-bn/index.html>



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/22/2020 6:56:31 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Fwd: OC-CBER meeting 1/23/20

FYI

Will miss this week's CBER check in due to need to support CTP on the ENDS front this week. If the Hill call moves, which it might, I will join.

Thanks!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:55:10 AM EST  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Peter, I am sorry to miss this week's check in as I will be on a call with Hill staff with Mitch on our ENDS Policy at the same time as your meeting. Let me know if helpful to touch base another time this week. Thanks!

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:16:44 AM EST  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** OC-CBER meeting 1/23/20

Dear Frank,

The agenda for tomorrow's OC-CBER meeting is as follows:

1. Coronavirus update
2. (b)(4) vaccine update
3. Upcoming DoD-CBER meeting
  - a. US Freeze Dried Plasma
  - b. French Freeze Dried Plasma
  - c. Other products (chilled platelets)
4. Stem cell compliance planning
  - a. Litigation update

b. Plans for facilitating adverse event reporting

Best Regards,  
Peter

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/22/2020 9:29:50 AM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: OC-CBER meeting 1/23/20

Thx Anna

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:56:32 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: OC-CBER meeting 1/23/20

FYI

Will miss this week's CBER check in due to need to support CTP on the ENDS front this week. If the Hill call moves, which it might, I will join.

Thanks!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:55:10 AM EST  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Peter, I am sorry to miss this week's check in as I will be on a call with Hill staff with Mitch on our ENDS Policy at the same time as your meeting. Let me know if helpful to touch base another time this week. Thanks!

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:16:44 AM EST  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** OC-CBER meeting 1/23/20

Dear Frank,

The agenda for tomorrow's OC-CBER meeting is as follows:

1. Coronavirus update
2. (b)(4) vaccine update
3. Upcoming DoD-CBER meeting
  - a. US Freeze Dried Plasma
  - b. French Freeze Dried Plasma
  - c. Other products (chilled platelets)
4. Stem cell compliance planning
  - a. Litigation update
  - b. Plans for facilitating adverse event reporting

Best Regards,  
Peter

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/22/2020 9:30:06 AM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]  
**Subject:** Re: OC-CBER meeting 1/23/20

Great work this morning

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:56:32 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: OC-CBER meeting 1/23/20

FYI

Will miss this week's CBER check in due to need to support CTP on the ENDS front this week. If the Hill call moves, which it might, I will join.

Thanks!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:55:10 AM EST  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Peter, I am sorry to miss this week's check in as I will be on a call with Hill staff with Mitch on our ENDS Policy at the same time as your meeting. Let me know if helpful to touch base another time this week. Thanks!

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:16:44 AM EST  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** OC-CBER meeting 1/23/20

Dear Frank,

The agenda for tomorrow's OC-CBER meeting is as follows:

1. Coronavirus update

2. (b)(4) vaccine update
3. Upcoming DoD-CBER meeting
  - a. US Freeze Dried Plasma
  - b. French Freeze Dried Plasma
  - c. Other products (chilled platelets)
4. Stem cell compliance planning
  - a. Litigation update
  - b. Plans for facilitating adverse event reporting

Best Regards,  
Peter

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/22/2020 9:41:11 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Re: OC-CBER meeting 1/23/20

Thank you

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** January 22, 2020 at 9:30:07 AM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Great work this morning

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:56:32 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: OC-CBER meeting 1/23/20

FYI

Will miss this week's CBER check in due to need to support CTP on the ENDS front this week. If the Hill call moves, which it might, I will join.

Thanks!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:55:10 AM EST  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Peter, I am sorry to miss this week's check in as I will be on a call with Hill staff with Mitch on our ENDS Policy at the same time as your meeting. Let me know if helpful to touch base another time this week. Thanks!

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:16:44 AM EST  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>

**Subject:** OC-CBER meeting 1/23/20

Dear Frank,

The agenda for tomorrow's OC-CBER meeting is as follows:

1. Coronavirus update
2. (b)(4) vaccine update
3. Upcoming DoD-CBER meeting
  - a. US Freeze Dried Plasma
  - b. French Freeze Dried Plasma
  - c. Other products (chilled platelets)
4. Stem cell compliance planning
  - a. Litigation update
  - b. Plans for facilitating adverse event reporting

Best Regards,  
Peter



---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 1/22/2020 12:13:23 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** \*\*TO BE RESCHEDULED in the fall\*\*\*HEVER 25 (03/05/2020) Received notification from HEVER that they are monitoring the Coronavirus situation and will review plans on a regular basis) They move to August/September or October  
**Attachments:** Commissioner External Event Request Form.doc; Hever Mission Statement October 2017 FINAL.pdf; Invitation for new FDA Commissioner to speak at Hever April 2020; Hever 25 Arrangements; Landscape Draft Hever 25 Agenda at 5 March.pdf; RE: Hever 25 Arrangements  
**Location:** Four Seasons Downtown Hotel, 27 Barclay Street, NY, NY 10007  
**Start:** 4/3/2020  
**End:** 4/4/2020  
**Show Time As:** Free

Confirmed on 03/11/2020 with organizer that Hotel was canceled. CMG

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 1/22/2020 12:13:23 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** \*\*TO BE RESCHEDULED in the fall\*\*\*HEVER 25 (03/05/2020) Received notification from HEVER that they are monitoring the Coronavirus situation and will review plans on a regular basis) They move to August/September or October  
**Attachments:** Commissioner External Event Request Form.doc; Hever Mission Statement October 2017 FINAL.pdf; Invitation for new FDA Commissioner to speak at Hever April 2020; Hever 25 Arrangements; Landscape Draft Hever 25 Agenda at 5 March.pdf; RE: Hever 25 Arrangements  
**Location:** Four Seasons Downtown Hotel, 27 Barclay Street, NY, NY 10007  
**Start:** 4/3/2020  
**End:** 4/4/2020  
**Show Time As:** Free

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 1/22/2020 12:13:23 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** \*\*TO BE RESCHEDULED in the fall\*\*\*HEVER 25 (03/05/2020) Received notification from HEVER that they are monitoring the Coronavirus situation and will review plans on a regular basis) They move to August/September or October  
**Attachments:** Commissioner External Event Request Form.doc; Hever Mission Statement October 2017 FINAL.pdf; Invitation for new FDA Commissioner to speak at Hever April 2020; Hever 25 Arrangements; Landscape Draft Hever 25 Agenda at 5 March.pdf  
**Location:** Four Seasons Downtown Hotel, 27 Barclay Street, NY, NY 10007  
**Start:** 4/3/2020  
**End:** 4/4/2020  
**Show Time As:** Free

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 1/22/2020 12:13:23 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** \*\*Cleared by ethics\*\*\*HEVER 25 (03/05/2020) Received notification from HEVER that they are monitoring the Coronavirus situation and will review plans on a regular basis) They move to August/September or October  
**Attachments:** Commissioner External Event Request Form.doc; Hever Mission Statement October 2017 FINAL.pdf; Invitation for new FDA Commissioner to speak at Hever April 2020; Hever 25 Arrangements; Landscape Draft Hever 25 Agenda at 5 March.pdf  
**Location:** Four Seasons Downtown Hotel, 27 Barclay Street, NY, NY 10007  
**Start:** 4/3/2020  
**End:** 4/4/2020  
**Show Time As:** Free

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 1/22/2020 12:13:23 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** \*\*Cleared by ethics\*\*\*HEVER 25 (03/05/2020) Received notification from HEVER that they are monitoring the Coronavirus situation and will review plans on a regular basis) They move to August/September or October  
**Attachments:** Draft Agenda at 13th January 2020 vs2.docx; Commissioner External Event Request Form.doc; Hever Mission Statement October 2017 FINAL.pdf; Invitation for new FDA Commissioner to speak at Hever April 2020; Hever 25 Arrangements  
**Location:** Four Seasons Downtown Hotel, 27 Barclay Street, NY, NY 10007  
**Start:** 4/3/2020  
**End:** 4/4/2020  
**Show Time As:** Free

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 1/22/2020 12:13:23 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** \*\*\*Pending Ethics Clearance\*\*\*HEVER 25 (03/05/2020) Received notification from HEVER that they are monitoring the Coronavirus situation and will review plans on a regular basis) They move to August/September or October  
**Attachments:** Draft Agenda at 13th January 2020 vs2.docx; Commissioner External Event Request Form.doc; Hever Mission Statement October 2017 FINAL.pdf; Invitation for new FDA Commissioner to speak at Hever April 2020; Hever 25 Arrangements  
**Location:** Four Seasons Downtown Hotel, 27 Barclay Street, NY, NY 10007  
**Start:** 4/3/2020  
**End:** 4/4/2020  
**Show Time As:** Free

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/22/2020 8:56:43 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: OC-CBER meeting 1/23/20

And I can join (previous Hill conflict was moved to next week). Thanks!

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Wednesday, January 22, 2020 9:30 AM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Thx Anna

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:56:32 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: OC-CBER meeting 1/23/20

FYI

Will miss this week's CBER check in due to need to support CTP on the ENDS front this week. If the Hill call moves, which it might, I will join.

Thanks!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:55:10 AM EST  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>  
**Subject:** Re: OC-CBER meeting 1/23/20

Peter, I am sorry to miss this week's check in as I will be on a call with Hill staff with Mitch on our ENDS Policy at the same time as your meeting. Let me know if helpful to touch base another time this week. Thanks!

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** January 22, 2020 at 6:16:44 AM EST  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>, Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>, Jenkins, Charlene <Charlene.Jenkins@fda.hhs.gov>

**Subject:** OC-CBER meeting 1/23/20

Dear Frank,

The agenda for tomorrow's OC-CBER meeting is as follows:

1. Coronavirus update
2. (b)(4) vaccine update
3. Upcoming DoD-CBER meeting
  - a. US Freeze Dried Plasma
  - b. French Freeze Dried Plasma
  - c. Other products (chilled platelets)
4. Stem cell compliance planning
  - a. Litigation update
  - b. Plans for facilitating adverse event reporting

Best Regards,  
Peter



---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 1/23/2020 5:09:51 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

**Subject:** Discussion: Historical Overview on FDA Response/Action (coronavirus)

**Location:** HHS-729D or 1-877-465-7975,, [redacted] (b)(6)

**Start:** 1/24/2020 12:15:00 PM

**End:** 1/24/2020 12:45:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Amin, Stacy; Shah, Anand

---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 1/23/2020 5:09:51 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

**Subject:** (HOLD) Discussion: Historical Overview on FDA Response/Action (coronavirus)

**Location:** HHS-729D or 1-877-465-7975,,, (b)(6)

**Start:** 1/24/2020 12:15:00 PM

**End:** 1/24/2020 12:45:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Amin, Stacy; Shah, Anand

**From:** vinu arumugham (b)(6)  
**Sent:** 1/24/2020 8:42:02 PM  
**To:** Slater, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2b00a57b0a747a9bc4f2317937a1022-slaterj]; Woo, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f70d0e3a7aaf442fb4962b61dde9894b-WooJ]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; CBER OCOD Consumer Account [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6d1fb37325043bcbe25183a0aaece3c-CBEROCOD]; DeStefano, Frank (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a799ec222e8741e988566e6141cbf1ba-HHS-fxd1-cd]; Thompson, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b2302812fa541759657b0569509577d-HHS-isq8-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Walker, Tanja Y (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ac93805a04cb2a742ec0845269e0f-HHS-hjn0-cd]; Secretary@HHS.gov; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; directorsincoming@cdc.gov; francis.collins@nih.gov; mrolfes1@cdc.gov; Doyle, Joshua D (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6f540756f5e4fb28f6342abb37adc80-HHS-xzd2-cd]; Blanton, Lenee H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af6c9acc0f6462e9ec15ac743cdc7-HHS-acy9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Tumpey, Terrence M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21ce7e7681c44913862a0b4829d19df6-HHS-tft9-cd]; Wentworth, David E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c0bcb905b046c28f7e56cd5f2c54f5-HHS-gll9-cd]; sharplessne@nih.hhs.gov; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Kretsinger, Katrina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e123d287c55c449d84c4e5dcafb80a33-HHS-kok4-cd]; Linkins, Robert (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ac11517f634867818d7a8882a915a1-HHS-rxl3-cd]; Epperson, Scott (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884f3347a42048deb11c01980beccbc2-HHS-gbq7-cd]; Andes, Linda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f7897f96c74f229c4795e534d64f17-HHS-fwf7-cd]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Emelia.Benjamin@bmc.org; mjessup@leducq.com; tavori@ohsu.edu; jessica.lilley@vanderbilt.edu; web@beasleyallen.com; dr.flegg@bfwhospitals.nhs.uk

**Subject:** Wuhan 2019-nCoV treatment; Vaccines induce autoimmunity: Epitope database evidence; Ebola vaccine will cause rice allergy epidemic

---

IgE mediated sensitization to peptides that have homology to 2019-nCoV peptides may contribute to disease severity. In that case, antihistamines and other allergy treatments such as mast cell stabilizers may help reduce infection severity.

A BLASTP analysis of 2019-nCoV proteome against common vaccine antigens was performed. Preliminary results suggest that IgE mediated sensitization to common vaccine antigens can result in cross reactive immune responses to 2019-nCoV.

Please see details of the mechanisms here:

Influenza vaccines and dengue-like disease

<https://www.bmj.com/content/360/bmj.k1378/rr-15>

<https://www.quora.com/Why-was-the-flu-so-deadly-in-outbreaks-in-the-past-And-what-made-the-flu-become-less-deadly/answers/86456279>

---

"Scientists" at the global vaccine safety summit spill the beans: There is no science behind vaccine safety claims, it's a fairy tale.

The party is over folks.

<https://youtu.be/s2IujhTdCLE>

---

ERVEBO Ebola vaccine will create a rice allergy epidemic, add to numerous autoimmune diseases, cancer and make Ebola disease even more severe. Design for safety and vaccine safety regulation remain abject failures. Incompetence or indifference?  
<https://doi.org/10.5281/zenodo.3595020>

---

Analyzing 23000+ epitopes covering 82 autoimmune diseases in the Immune Epitope Database, 57% have only one and 78% have up to two amino acid residue differences compared to animal, fungal or plant peptides present in vaccines; an unmistakable signature of the role of vaccines in their etiologies  
<https://doi.org/10.5281/zenodo.3603480>

**Analyzing 23000+ epitopes covering 82 autoimmune diseases in the Immune Epitope Database, 57% have only one and 78% have up to two amino acid residue differences compared to animal, fungal or plant peptides present in vaccines; an unmistakable signature of the role of vaccines in their etiologies**

Vinu Arumugham

## Lay summary

Proteins are a chain of amino acids. Proteins can have up to several hundred amino acids. Snippets of proteins (peptides), 7-15 amino acids in length are important in immunology. There are 20 types of amino acids. Each is assigned a letter (1 letter code).

Antibodies are proteins that can bind to peptides that have a specific amino acid sequence. Such a target peptide is known as an epitope. When an antibody binds to a peptide (which is part of a protein, which in turn may be part of a cell surface), it can trigger an immune attack on the cell. If the cell were a bacterium, the bacterium would be killed.

Humans (like all organisms) are made of numerous proteins (self proteins). So we have self-proteins, self-peptides and self-epitopes. In a healthy person, the body will not make antibodies that bind strongly to self-peptides (self-tolerance).

DNA is a chain of base-pairs. The DNA base-pair sequence determines the amino acid sequence in the protein produced. If there is a mutation that alters a single base-pair, the resulting protein will have a single amino acid that is altered. To prevent cancer, the immune system is capable of making antibodies against such altered peptides. Such antibodies can also weakly bind (cross react) to the unaltered normal peptide thus resulting in destruction of some healthy cells.

Say a normal protein has the following peptide (10 amino acids, each represented by its 1 letter code):

ALSTLVVNKI

Say DNA in a cell mutates due to a carcinogen exposure and it alters the protein thus resulting in this peptide with a single amino acid change:

ALSTLVVSKI

When the immune system makes antibodies targeted at ALSTLVVSKI (to attack the cell with the DNA mutation), the same antibodies can weakly bind to the normal ALSTLVVNKI peptide.

ALSTLVVNKI is an epitope associated with rheumatoid arthritis (RA).

So as a result of the immune system defending against cancer, the person can develop RA.

Now consider vaccines containing animal proteins. Animal proteins are very similar to human proteins, containing only occasional amino acid differences. An animal peptide could therefore have the ALSTLVVSKI sequence. Such a vaccine would fool the immune system into creating an anti-cancer immune response, creating antibodies targeted at ALSTLVVSKI. The result is vaccine induced RA.

Therefore one can predict that analyzing epitopes associated with autoimmune diseases, such single amino acid difference compared to animal peptides present in vaccines, would occur more frequently than can be expected merely by chance. The analysis confirms that this prediction is valid.

## Abstract

The National Institute of Allergy and Infectious Diseases (NIAID) sponsors the Immune Epitope Data Base (IEDB). IEDB contains epitopes identified from the medical literature and organized by diseases and categories of diseases. All epitopes (23000+) associated with 82 autoimmune diseases in humans were analyzed.

The role of animal, plant, fungal proteins contained in vaccines in the etiology of autoimmune diseases have been described in humans and animals. BLASTP was used to analyze IEDB derived epitopes for sequence alignment to animal, plant, fungal (APF) proteins present in vaccines and biologics. Specifically, the search was performed against bovine, chicken, porcine, guinea pig, African green monkey, Chinese hamster, murine, peanut, soy, wheat, corn, sesame and *Saccharomyces cerevisiae* proteomes.

The results show that 57% of epitopes differed by exactly one amino acid residue from an APF peptide. 78% of the epitopes differed by up to two amino acid residues from an APF peptide. The rest of the epitopes were either identical or differed by more than two amino acid residues.

A majority of IEDB epitopes analyzed were 9-mer peptides. Comparing randomly selected 9-mer human peptides with APF proteomes, the probability of single amino acid residue difference (SAARD) outcomes was derived. This was used to estimate the probability that actual IEDB SAARD alignments to APF peptides were merely a chance outcome. The estimates show that the probability that the observed IEDB alignments to APF being merely a chance outcome are vanishingly small. So the results make it absolutely clear that APF proteins in vaccines cause all these autoimmune diseases.

## **Introduction**

Vaccines contain thousands of residual animal, plant and fungal (APF) proteins from the manufacturing process (1–6). 293 chicken proteins were identified in the influenza vaccine (7), for example. Actin and vimentin proteins were detected in the Priorix Tetra vaccine (8). Immunization with homologous xenogeneic antigens resulting in autoimmune diseases has been known for at least 40 years (9). Vaccines that contain bovine proteins caused autoimmunity in dogs (10). We previously described the immunological mechanism involved in autoimmunity induction by immunization with homologous xenogeneic antigens (11).

Cancer cells have minor differences when compared to healthy cells. Due to mutation of the DNA encoding the proteins, cancer cells can display altered proteins on their surface. Healthy cancer defense mechanisms include immune responses directed at such altered proteins. Therefore an immune response directed against cancer cells always carries a risk of cross reactive immune responses against healthy cells displaying the unaltered protein. Therefore, cancer induced autoimmune responses are a consequence of normal, healthy immune system behavior.

Animal proteins have minor differences compared to human proteins. Peptides that are identical between humans and animals are unlikely to cause any problem due to strong self tolerance. However, peptides with one amino acid residue difference produce the strongest cross reactive immune responses (11). They are ideally suited to induce autoimmune diseases. Injecting animal proteins results in anti-cancer immune responses because the immune system perceives animal proteins as altered human proteins. Adjuvants in the vaccine boost this anti-cancer immune response. This artificial anti-cancer response directed at thousands of APF proteins in vaccines or biologics, therefore cross react and cause numerous autoimmune disorders.

For this reason, one can predict that single amino acid residue difference (SAARD) between autoimmune disease related epitopes in the IEDB and homologous APF peptides in vaccines, would occur at a higher probability than by mere chance. We perform a BLASTP analysis to verify.

## **Methods**

Basic local alignment search tool for proteins (BLASTP) (12), Universal Protein Resource (UniProt)(13) and the Immune Epitope Database (IEDB) (14) were used for bioinformatics analysis.

Specifically, the BLASTP sequence alignment of IEDB peptides was performed against bovine, chick, porcine, guinea pig, African green monkey, Chinese hamster, murine, peanut, soy, wheat, corn, sesame and *Saccharomyces cerevisiae* proteomes. Vaccines and biologics contain residual proteins from all these organism due to media used to grow viruses or bacteria, recombinant cells/organisms used for protein expression or as excipients.

## Results

57% of IEDB peptides have a SAARD and 78% have up to two amino acid differences compared to animal, fungal or plant peptides present in vaccines.

## Discussion

Could this result be a chance occurrence?

A majority of IEDB epitopes analyzed were 9-mer peptides. Five thousand 9-mer peptides were chosen at random from the human proteome. BLASTP was run using these peptides to compare against each organism's proteome or a subset. This provides us the probability that randomly selected human peptides have an alignment providing a SAARD compared to peptides from these organisms. These are listed in table 1 under "Random SAARD alignment". Given this, we can compute the probability of the actual SAARD alignment to IEDB epitopes, occurring by chance. This is listed in table 1 under "Estimated probability of actual SAARD outcome occurring just by chance".

For a simple coin toss example, we would perform the calculation as follows:

Computing probability of say a 7 heads, 3 tails outcome of 10 trials of a fair coin:

$$\text{Probability} = (0.5^7) \times (0.5^3) \times 10! / (7! \times 3!)$$

Where:

0.5 is the probability of a head or tail outcome of a fair coin.

For an unfair coin, say probability of head outcome = 0.4 and tail outcome 0.6, we would have:

$$\text{Probability} = (0.4^7) \times (0.6^3) \times 10! / (7! \times 3!)$$

For the IEDB peptide probability analysis, the outcome is for 23192 trials (peptides).

The "head outcome" is the "Random SAARD alignment" entries in table 1. The "tail outcome" probability is 1-"head outcome".

Sample calculation for Chinese Hamster:

$$\text{Probability} = ((889/5000)^{4574}) \times ((4111/5000)^{18618}) \times 23192! / (4574! \times 18618!)$$

$$\text{Probability} = 1.488\text{e-}15$$

Where:  $889 \times 100 / 5000 = 17.8\%$  is the entry in Table 1 for Chinese Hamster. BLASTP analysis shows 889 SAARD out of 5000 peptides analyzed.

And,  $4574 \times 100 / 23192 = 19.7\%$  is the IEDB entry in Table 1 for Chinese Hamster. BLASTP analysis shows 4574 SAARD out of 23192 peptides analyzed.

So the 1.488e-15 value is the probability that we will have exactly 4574 SAARD alignments out of 23192 peptides. The probability goes down for all values > 4574. Conservatively, applying the same probability as for 4574, to all values >4574, we can calculate the probability of the chance occurrence of 4574 or greater number of SAARD alignments as  $1.488e15 * 18618 = 27e-12$ , entry in table.

The Gnome calculator was used to perform these calculations and the results were verified using the Qalculate! calculator and WolframAlpha (15) since spreadsheets are unable to perform these calculations.

**Table 1**

| Organism                                             | Random SAARD alignment Number of Peptides(%) | Actual (IEDB) SAARD alignment Number of Peptides (%) | Estimated probability of actual SAARD outcome occurring just by chance | Remarks                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------|----------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| African green monkey ( <i>Chlorocebus aethiops</i> ) | 26 (0.5)                                     | 420 (1.8)                                            | ~1.7e-96                                                               | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                                                                                     |
| Cow ( <i>Bos taurus</i> )                            | 936 (18.7)                                   | 4385 (18.9)                                          | ~1                                                                     | There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all cow proteins are present in the vaccines in equal amount is not true. We know that cow's milk, bovine gelatin, bovine serum albumin are used in vaccines. So these proteins and proteins present in tissues in the vicinity, are included in vaccines but other cow proteins may not be present. This is the more likely explanation. Please see Cow's milk entry below. |
| Cow's Milk ( <i>Bos taurus</i> )                     | 0 (0)                                        | 12 (0.05)                                            | 0                                                                      | Probability of this outcome occurring just by chance is 0. So these animal proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                                                                                                     |
| Chinese Hamster ( <i>Cricetulus griseus</i> )        | 889 (17.8)                                   | 4574 (19.7)                                          | ~27e-12                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, biologics caused these diseases.                                                                                                                                                                                                                                                                                                                           |
| Chicken ( <i>Gallus gallus</i> )                     | 536 (10.7)                                   | 3901 (16.8)                                          | <1e-100                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases. Unlike bovine, porcine and                                                                                                                                                                                                                                                                                                          |



| Organism                                  | Random SAARD alignment Number of Peptides(%) | Actual (IEDB) SAARD alignment Number of Peptides (%) | Estimated probability of actual SAARD outcome occurring just by chance | Remarks                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------|----------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                           |                                              |                                                      |                                                                        | murine proteins, since chicken egg or embryo is used for vaccine manufacture, all chicken proteins can be present in vaccines.                                                                                                                                                                                                                                                                             |
| Guinea Pig ( <i>Cavia porcellus</i> )     | 837 (16.7)                                   | 4439 (19.1)                                          | ~1e-18                                                                 | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                    |
| Mice ( <i>Mus musculus</i> )              | 940 (18.8)                                   | 4467 (19.3)                                          | ~1                                                                     | There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all mice proteins are present in biologics in equal amount is not true. We know that mice myeloma cells are used in biologics. So these proteins and proteins present in tissues in the vicinity, are present in biologics but other mice proteins may not be present. This is the more likely explanation. |
| Maize ( <i>Zea mays</i> )                 | 303 (6.1)                                    | 1667 (7.2)                                           | ~5e-9                                                                  | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                     |
| Peanut ( <i>Arachis hypogaea</i> )        | 223 (4.5)                                    | 1697 (7.3)                                           | ~79e-81                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                     |
| Yeast ( <i>Saccharomyces cerevisiae</i> ) | 64 (1.3)                                     | 828 (3.6)                                            | <1e-100                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these fungal proteins in vaccines, biologics caused these diseases.                                                                                                                                                                                                                                                          |
| Sesame ( <i>Sesamum indicum</i> )         | 155 (3.1)                                    | 1398 (6.0)                                           | <1e-100                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                     |
| Soy ( <i>Glycine max</i> )                | 215 (4.3)                                    | 1548 (6.7)                                           | ~86e-59                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these                                                                                                                                                                                                                                                                                                                        |

| Organism                           | Random SAARD alignment Number of Peptides(%) | Actual (IEDB) SAARD alignment Number of Peptides (%) | Estimated probability of actual SAARD outcome occurring just by chance | Remarks                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------|----------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pig ( <i>Sus scrofa</i> )          | 963 (19.3)                                   | 4407 (19.0)                                          | ~1                                                                     | plant proteins in vaccines, caused these diseases.<br><br>There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all porcine proteins are present in the vaccines in equal amount is not true. We know that porcine gelatin is used in vaccines. So these proteins and proteins present in tissues in the vicinity are included in vaccines but other porcine proteins may not be present. This is the more likely explanation. |
| Wheat ( <i>Triticum aestivum</i> ) | 138 (2.8)                                    | 977 (4.2)                                            | ~18e-33                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                                                                                  |

The calculations make it clear that the findings cannot be merely a chance outcome and that immunization against animal/plant/fungal antigens in the vaccines do cause these autoimmune diseases in the IEDB.

## Conclusion

Vaccines containing animal, plant or fungal proteins are extremely dangerous and cause numerous autoimmune diseases and cancer (16–19). All non-target proteins in vaccines must be immediately removed using processes such as affinity chromatography (20).

## References

1. Kattan JD, Cox AL, Nowak-Wegrzyn A, Gimenez G, Bardina L, Sampson HA, et al. Allergic reactions to diphtheria, tetanus, and acellular pertussis vaccines among children with milk allergy. *J Allergy Clin Immunol*. 2011;Conference(var.pagings):AB238.
2. Arumugham V. Oxford Vaccine Group Vaccine Knowledge Project's Vaccine Ingredient and vaccine safety misinformation exposed [Internet]. 2019 [cited 2019 Dec 11]. Available from: <https://doi.org/10.5281/zenodo.3477854>
3. National Academies of Sciences and Medicine E. Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy. Stallings VA, Oria MP, editors. Washington, DC: The National Academies Press; 2017.

4. Gardasil Package Insert [Internet]. Available from:  
<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf>
5. ENGERIX-B HIGHLIGHTS OF PRESCRIBING INFORMATION [Internet]. Available from:  
<https://www.fda.gov/media/79341/download>
6. Arumugham V, Trushin M V. Role of NMDA receptor autoimmunity induced by food protein containing vaccines, in the etiology of autism, type 1 diabetes, neuropsychiatric and neurodegenerative disorders [Internet]. *International Journal of Pharmaceutical Research*. 2019 [cited 2019 Apr 15]. p. 428–37. Available from:  
<https://doi.org/10.5281/zenodo.1463600>
7. Jacob L, Leib R, Ollila HM, Bonvalet M, Adams CM, Mignot E. Comparison of Pandemrix and Arepanrix, two pH1N1 AS03-adjuvanted vaccines differentially associated with narcolepsy development. *Brain Behav Immun*. 2015 Jul;47:44–57.
8. Corvelva. Vaccinegate: Study on the chemical composition profile of Priorix Tetra [Internet]. 2018 [cited 2019 Aug 24]. Available from: <https://drive.google.com/file/d/1cNtdBczAX1-xowPEDep1kZOjy84IypAB/view>
9. Arumugham V. Vaccination with bovine, chick, yeast antigens synthesizes cross-reactive antibodies targeting human acetylcholine receptor and MuSK protein to cause Myasthenia Gravis: Confirmed by natural experiment (VAERS data), bioinformatics, case reports, animal experiments and titer study [Internet]. 2019 [cited 2019 Sep 16]. Available from: <https://doi.org/10.5281/zenodo.3421558>
10. Hogenesch H, Azcona-Olivera J, Scott-Moncrieff C, Snyder PW, Glickman LT. Vaccine-induced autoimmunity in the dog. *Adv Vet Med*. 1999;41:733–47.
11. Arumugham V, Trushin M V. Cancer immunology, bioinformatics and chemokine evidence link vaccines contaminated with animal proteins to autoimmune disease: a detailed look at Crohn’s disease and Vitiligo. *J Pharm Sci Res*. 2018;10(8):2106.
12. Altschul SF, Madden TL, Schäffer AA, Zhang J, Zhang Z, Miller W, et al. Gapped BLAST and PSI-BLAST: a new generation of protein database search programs. *Nucleic Acids Res*. 1997;25(17):3389–402.
13. UniProt: the universal protein knowledgebase. *Nucleic Acids Res*. 2017 Jan 4;45(D1):D158–69.
14. Vita R, Mahajan S, Overton JA, Dhanda SK, Martini S, Cantrell JR, et al. The Immune Epitope Database (IEDB): 2018 update. *Nucleic Acids Res*. Oxford University Press; 2019;47(D1):D339–43.
15. Wolfram|Alpha: Computational Intelligence [Internet]. [cited 2020 Jan 8]. Available from:  
<https://www.wolframalpha.com/>
16. Arumugham V. Vaccines and Biologics injury table based on mechanistic evidence – Mar 2019 [Internet]. 2019 [cited 2019 May 16]. Available from:  
<https://zenodo.org/record/2582635/files/viittoc0302http.pdf?download=1>
17. Arumugham V. As predicted, animal protein containing biologics induce de novo autoimmune disorders [Internet]. 2019 [cited 2019 Dec 29]. Available from: <https://doi.org/10.5281/zenodo.3483322>
18. Arumugham V. Expanding ASIA to GAVIDOTTIR : GAmut of Vaccine Induced Damage emphasizing Off Target Immune Responses [Internet]. 2019 [cited 2019 Oct 23]. Available from:  
<https://doi.org/10.5281/zenodo.3478840>

19. Arumugham V. Role of anti-carbonic anhydrase 2 antibodies induced by vaccine antigens, in the etiology of acute myeloid leukemia and other malignancies [Internet]. 2019 [cited 2019 Nov 14]. Available from: <https://doi.org/10.5281/zenodo.3534442>
20. Zhao M, Vandersluis M, Stout J, Haupts U, Sanders M, Jacquemart R. Affinity chromatography for vaccines manufacturing: Finally ready for prime time? Vaccine. Netherlands; 2018 Apr;

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/26/2020 12:00:08 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Fwd: Third US case of coronavirus confirmed as China warns people can spread the virus before realizing they're ill

FYI

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Date:** January 26, 2020 at 10:46:15 AM EST  
**To:** Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Fisher, Robert <Robert.Fisher@fda.hhs.gov>, Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>, Roth, Kristian <Kristian.Roth@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>, Rouse, David <David.Rouse@fda.hhs.gov>, Styr, Barbara <Barbara.Styr@fda.hhs.gov>, Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** Third US case of coronavirus confirmed as China warns people can spread the virus before realizing they're ill

<https://www.cnn.com/2020/01/26/us/coronavirus-orange-county/index.html>

---

**From:** Janik, Heather [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117BC4D27D7B47DDBEBEE5FFEEB7F3D-HEATHER.JAN]  
**Sent:** 1/26/2020 1:44:06 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** FW: Updated Briefer & For Review  
**Attachments:** coronavirus-graphic2.jpg; SH Washington Post Interview 1.27.2020\_UPDATED.pdf; Gene Therapy Statement for SH Review.docx

Hi Dr. Hahn,

The below message includes the coronavirus tweet thread at close (graphic is attached), as well as a revised briefer and the gene therapy statement for review.

Thank you!

Heather

---

**From:** Janik, Heather

**Sent:** Saturday, January 25, 2020 10:12 AM

Hi Dr. Hahn,

My apologies, when creating your Washington Post briefer last night I accidentally used outdated talking points. Please use the updated version attached as you prepare- it has new messaging expanding on your priorities and also the policy areas Laurie expressed interest.

Additionally, the following are included for your review:

- A coronavirus tweet thread with graphic (below). The content has been signed off by Anand and Anna. Please provide edits by 9 am Monday to ensure timely posting.
- The joint Gene Therapy statement from you and Dr. Marks that is slated for release Tuesday morning is attached for your review. Please provide edits by 9 am Monday on this, as well. We do have developed social media to accompany this statement that is still in the review process. I will share when ready.

My apologies again on the WaPo briefer and thank you!

Heather

CORONAVIRUS TWITTER THREAD for @SteveFDA

Tweet 1 of THREAD

At the FDA, we are working hard to prepare, mitigate & respond to #coronavirus, in close coordination with our federal partners. This collaboration, as @SecAzar noted, reflects our shared commitment to public health.

TWEET 2 of THREAD

We're committed to providing critical support alongside @HHSgov to all efforts- domestic and international- to prepare for & respond to the #coronavirus outbreak and ensure that safe and effective medical countermeasures are available as quickly as possible to protect public health.

TWEET 3 of THREAD

As with any emerging public health concern, @US\_FDA will collaborate with our interagency partners, product developers and international partners to expedite development and availability of tools needed to diagnose, treat, mitigate, and prevent outbreaks.

**Heather Janik**

*Assistant Commissioner, Office of Media Affairs*

**Office of External Affairs**

**U.S. Food and Drug Administration**

Office (240) 402-3789 Cell (301) 538-4156

heather.janik@fda.hhs.gov



---

**From:** Janik, Heather [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117BC4D27D7B47DDBEBEEEE5FFEEB7F3D-HEATHER.JAN]  
**Sent:** 1/26/2020 1:45:31 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: Updated Briefer & For Review

No problem, thank you!

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Sunday, January 26, 2020 1:44 PM  
**To:** Janik, Heather <Heather.Janik@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: Updated Briefer & For Review

Heather,  
Now I see it. The coronavirus tweet thread with graphic looks good to me. Sorry for missing it.  
Steve

---

**From:** "Janik, Heather" <Heather.Janik@fda.hhs.gov>  
**Date:** Saturday, January 25, 2020 at 10:11 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Laura Caliguiri <Laura.Caliguiri@fda.hhs.gov>, Frank Olivarria <Frank.Olivarria@fda.hhs.gov>, Heidi Rebello <Heidi.Rebello@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Subject:** Updated Briefer & For Review

Hi Dr. Hahn,  
My apologies, when creating your Washington Post briefer last night I accidentally used outdated talking points. Please use the updated version attached as you prepare- it has new messaging expanding on your priorities and also the policy areas Laurie expressed interest.

Additionally, the following are included for your review:

- A coronavirus tweet thread with graphic (below). The content has been signed off by Anand and Anna. Please provide edits by 9 am Monday to ensure timely posting.
- The joint Gene Therapy statement from you and Dr. Marks that is slated for release Tuesday morning is attached for your review. Please provide edits by 9 am Monday on this, as well. We do have developed social media to accompany this statement that is still in the review process. I will share when ready.

My apologies again on the WaPo briefer and thank you!

Heather

CORONAVIRUS TWITTER THREAD for @SteveFDA



**Tweet 1 of THREAD**

At the FDA, we are working hard to prepare, mitigate & respond to #coronavirus, in close coordination with our federal partners. This collaboration, as @SecAzar noted, reflects our shared commitment to public health.

**TWEET 2 of THREAD**

We're committed to providing critical support alongside @HHSgov to all efforts- domestic and international- to prepare for & respond to the #coronavirus outbreak and ensure that safe and effective medical countermeasures are available as quickly as possible to protect public health.

**TWEET 3 of THREAD**

As with any emerging public health concern, @US\_FDA will collaborate with our interagency partners, product developers and international partners to expedite development and availability of tools needed to diagnose, treat, mitigate, and prevent outbreaks.

**Heather Janik**

*Assistant Commissioner, Office of Media Affairs*

**Office of External Affairs**

**U.S. Food and Drug Administration**

Office (240) 402-3789 Cell (301) 538-4156

heather.janik@fda.hhs.gov



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/26/2020 6:43:20 PM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeb7f3d-Heather.Jan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

It does  
Thx much

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 26, 2020 at 6:35:51 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

And just confirmed with the team that the EUA request has not come in yet from CDC and we do not disclose EUA requests, just when we issue them.

Hope this clarification helps!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 26, 2020 at 5:38:36 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

Plus Heather and Denise.

As of Friday we were preparing to receive a request for an EUA from CDC anticipating it is coming, but it had not yet come in. Checking with the team is see if it has come in since we last connected on this specific point, but this would have been flagged given the significance. And not to pre-judge the regulatory decision making with respect to any potential EUA, but issuance of EUA would rise to a Commissioner level statement.

The reference at the end is very general and encompasses FDA's work with diagnostic developers, including CDC, to develop and make available the reference materials necessary to help with development of diagnostics.

(b)(5)

(b)(5)

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Date:** January 26, 2020 at 5:05:31 PM EST

**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Subject:** FW: 5 cases of Wuhan virus confirmed in U.S., with more expected

(b)(5)

Wasn't the EUA for the diagnostic issued?

Steve

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>

**Reply-To:** POLITICO subscriptions <reply-fe971c727160017c75-553241\_HTML-1027883907-1376319-204078@politicoemail.com>

**Date:** Sunday, January 26, 2020 at 4:18 PM

**To:** Stephen Hahn <SH1@fda.hhs.gov>

**Subject:** CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected

**CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected**

By Sarah Ower Mohle

01/26/2020 04:17 PM EST

Five people in the U.S. are infected with the Wuhan coronavirus, CDC said today.

Those include two newly confirmed cases in California and one in Arizona. CDC last week said a person in Illinois and a person in Washington state were infected. All five had recently traveled from Wuhan, China, the epicenter of the virus.

Another 100 people in the U.S. are being monitored for possible infection, though many will be ruled out, CDC's Nancy Messonnier, who leads the National Center for Immunization and Respiratory Diseases, said on a call with reporters.

Still, she warned that officials expect more U.S. cases, including person-to-person transmission.

Health officials are continuing to prepare for the Wuhan virus to be a pandemic but hope it is not, she said.

Messonnier called the situation in China "alarming" but applauded officials there for working to contain the virus. At least 56 people have died and nearly 2,000 are infected. Chinese authorities early last week shut down travel in and out of Wuhan and neighboring cities; this weekend, they announced tour groups out of China would also be banned until the contagion was under control.

Messonnier said the CDC is working rapidly with the FDA to prepare a diagnostic test that can be distributed throughout the U.S., but it still could be a matter of weeks before it's ready.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/01/cdc-5-cases-of-wuhan-virus-confirmed-in-us-with-more-expected-3976001>

**You received this POLITICO Pro content because your customized settings include: FDA. To change your alert**

settings, please go to <https://subscriber.politicopro.com/settings>.

---



This email alert has been sent for the exclusive use of POLITICO Pro subscriber, sh1@fda.hhs.gov. Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to [politicopro.com](https://politicopro.com).

---

This email was sent to sh1@fda.hhs.gov by:

POLITICO, LLC

1000 Wilson Blvd.

Arlington, VA 22209

USA .

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 1/26/2020 6:43:29 PM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeb7f3d-Heather.Jan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

It does  
Thx much

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 26, 2020 at 6:35:51 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

---

**From:** Janik, Heather [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117BC4D27D7B47DDBEBE5FFEEB7F3D-HEATHER.JAN]  
**Sent:** 1/26/2020 6:45:50 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** RE: 5 cases of Wuhan virus confirmed in U.S., with more expected

Agree. Anna, we have very similar language in the draft FIB- let me know if that meets what you need.  
Thanks!

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Sunday, January 26, 2020 6:44 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

(b)(5)

Heather?

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 26, 2020 at 5:38:36 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

Plus Heather and Denise.

As of Friday we were preparing to receive a request for an EUA from CDC anticipating it is coming, but it had not yet come in. Checking with the team is see if it has come in since we last connected on this specific point, but this would have been flagged given the significance. And not to pre-judge the regulatory decision making with respect to any potential EUA, but issuance of EUA would rise to a Commissioner level statement.

The reference at the end is very general and encompasses FDA's work with diagnostic developers, including CDC, to develop and make available the reference materials necessary to help with development of diagnostics.

(b)(5)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** January 26, 2020 at 5:05:31 PM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: 5 cases of Wuhan virus confirmed in U.S., with more expected

(b)(5)

Wasn't the EUA for the diagnostic issued?

Steve

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>  
**Reply-To:** POLITICO subscriptions <reply-fe971c727160017c75-553241\_HTML-1027883907-1376319-204078@politicoemail.com>  
**Date:** Sunday, January 26, 2020 at 4:18 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected

-  
**CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected**

By Sarah Oweremohle

01/26/2020 04:17 PM EST

Five people in the U.S. are infected with the Wuhan coronavirus, CDC said today.

Those include two newly confirmed cases in California and one in Arizona. CDC last week said a person in Illinois and a person in Washington state were infected. All five had recently traveled from Wuhan, China, the epicenter of the virus.

Another 100 people in the U.S. are being monitored for possible infection, though many will be ruled out, CDC's Nancy Messonnier, who leads the National Center for Immunization and Respiratory Diseases, said on a call with reporters.

Still, she warned that officials expect more U.S. cases, including person-to-person transmission.

Health officials are continuing to prepare for the Wuhan virus to be a pandemic but hope it is not, she said.

Messonier called the situation in China "alarming" but applauded officials there for working to contain the virus. At least 56 people have died and nearly 2,000 are infected. Chinese authorities early last week shut down travel in and out of Wuhan and neighboring cities; this weekend, they announced tour groups out of China would also be banned until the contagion was under control.

Messonier said the CDC is working rapidly with the FDA to prepare a diagnostic test that can be distributed throughout the U.S., but it still could be a matter of weeks before it's ready.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/01/cdc-5-cases-of-wuhan-virus-confirmed-in-us-with-more-expected-3976001>

**You received this POLITICO Pro content because your customized settings include: FDA. To change your alert settings, please go to <https://subscriber.politicopro.com/settings>.**



This email alert has been sent for the exclusive use of POLITICO Pro subscriber, sh1@fda.hhs.gov. Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to [politicopro.com](http://politicopro.com).

---

This email was sent to sh1@fda.hhs.gov by:  
POLITICO, LLC  
1000 Wilson Blvd.  
Arlington, VA 22209  
USA ■



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/26/2020 7:12:05 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

(b)(5)

It's accurate and very high level. I'm ok with it, but want to make sure we amplify appropriately. The Commissioner tweets help on that front.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** January 26, 2020 at 6:39:11 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

Anna: (b)(5)

Sent from my iPhone

On Jan 26, 2020, at 5:05 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

(b)(5)

Wasn't the EUA for the diagnostic issued?

Steve

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>  
**Reply-To:** POLITICO subscriptions <reply-fe971c727160017c75-553241\_HTML-1027883907-1376319-204078@politicoemail.com>  
**Date:** Sunday, January 26, 2020 at 4:18 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected

**CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected**

By Sarah Oweremohle

01/26/2020 04:17 PM EST

Five people in the U.S. are infected with the Wuhan coronavirus, CDC said today.

Those include two newly confirmed cases in California and one in Arizona. CDC last week said a person in Illinois and a person in Washington state were infected. All five had recently traveled from Wuhan, China, the epicenter of the virus.

Another 100 people in the U.S. are being monitored for possible infection, though many will be ruled out, CDC's Nancy Messonnier, who leads the National Center for Immunization and Respiratory Diseases, said on a call with reporters.

Still, she warned that officials expect more U.S. cases, including person-to-person transmission.

Health officials are continuing to prepare for the Wuhan virus to be a pandemic but hope it is not, she said.

Messonier called the situation in China "alarming" but applauded officials there for working to contain the virus. At least 56 people have died and nearly 2,000 are infected. Chinese authorities early last week shut down travel in and out of Wuhan and neighboring cities; this weekend, they announced tour groups out of China would also be banned until the contagion was under control.

Messonier said the CDC is working rapidly with the FDA to prepare a diagnostic test that can be distributed throughout the U.S., but it still could be a matter of weeks before it's ready.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/01/cdc-5-cases-of-wuhan-virus-confirmed-in-us-with-more-expected-3976001>

**You received this POLITICO Pro content because your customized settings include: FDA. To change your alert settings, please go to <https://subscriber.politicopro.com/settings>.**



This email alert has been sent for the exclusive use of POLITICO Pro subscriber, sh1@fda.hhs.gov. Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to [politicopro.com](http://politicopro.com).

---

This email was sent to sh1@fda.hhs.gov by:  
POLITICO, LLC  
1000 Wilson Blvd.  
Arlington, VA 22209  
USA

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 1/27/2020 5:31:04 AM  
**To:** Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: 5 cases of Wuhan virus confirmed in U.S., with more expected

Much appreciated, Anna/Heather.

Thanks,

Denise

---

**From:** Janik, Heather <Heather.Janik@fda.hhs.gov>  
**Date:** January 27, 2020 at 5:18:30 AM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** RE: 5 cases of Wuhan virus confirmed in U.S., with more expected

Thanks, Anna. Sounds good and I'll edit accordingly first thing this AM and move forward. Thanks!

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** January 26, 2020 at 11:09:38 PM EST  
**To:** Janik, Heather <Heather.Janik@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** RE: 5 cases of Wuhan virus confirmed in U.S., with more expected

Just sent back edits on the fib under separate cover to you (Heather)

(b)(5)

(b)(5)

Thanks!

Internal confidential

---

**From:** Abram, Anna

**Sent:** Sunday, January 26, 2020 6:52 PM

**To:** Janik, Heather <Heather.Janik@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Subject:** RE: 5 cases of Wuhan virus confirmed in U.S., with more expected

Will look at the fib tonight.

---

**From:** Janik, Heather <Heather.Janik@fda.hhs.gov>

**Date:** January 26, 2020 at 6:45:53 PM EST

**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Subject:** RE: 5 cases of Wuhan virus confirmed in U.S., with more expected

Agree. Anna, we have very similar language in the draft FIB- let me know if that meets what you need.

Thanks!

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Sent:** Sunday, January 26, 2020 6:44 PM

**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

(b)(5)

Anna. Heather?

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>

**Date:** January 26, 2020 at 5:38:36 PM EST

**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Subject:** Re: 5 cases of Wuhan virus confirmed in U.S., with more expected

Plus Heather and Denise.

As of Friday we were preparing to receive a request for an EUA from CDC anticipating it is coming, but it had not yet come in. Checking with the team is see if it has come in since we last connected on this specific point, but this would have been flagged given the significance. And not to pre-judge the regulatory decision making with respect to any potential EUA, but issuance of EUA would rise to a Commissioner level statement.

The reference at the end is very general and encompasses FDA's work with diagnostic developers, including CDC, to develop and make available the reference materials necessary to help with development of diagnostics.

(b)(5)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** January 26, 2020 at 5:05:31 PM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: 5 cases of Wuhan virus confirmed in U.S., with more expected

(b)(5)

Wasn't the EUA for the diagnostic issued?

Steve

---

**From:** POLITICO Pro Health Care <politicoemail@politicopro.com>  
**Reply-To:** POLITICO subscriptions <reply-fe971c727160017c75-553241 HTML-1027883907-1376319-204078@politicoemail.com>  
**Date:** Sunday, January 26, 2020 at 4:18 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected

**CDC: 5 cases of Wuhan virus confirmed in U.S., with more expected**

By Sarah Oweremohle

01/26/2020 04:17 PM EST

Five people in the U.S. are infected with the Wuhan coronavirus, CDC said today.

Those include two newly confirmed cases in California and one in Arizona. CDC last week said a person in Illinois and a person in Washington state were infected. All five had recently traveled from Wuhan, China, the epicenter of the virus.

Another 100 people in the U.S. are being monitored for possible infection, though many will be ruled out, CDC's Nancy Messonnier, who leads the National Center for Immunization and Respiratory Diseases, said on a call with reporters.

Still, she warned that officials expect more U.S. cases, including person-to-person transmission.

Health officials are continuing to prepare for the Wuhan virus to be a pandemic but hope it is not, she said.

Messonier called the situation in China "alarming" but applauded officials there for working to contain the virus. At least 56 people have died and nearly 2,000 are infected. Chinese authorities early last week shut down travel in and out of Wuhan and neighboring cities; this weekend, they announced tour groups out of China would also be banned until the contagion was under control.

Messonier said the CDC is working rapidly with the FDA to prepare a diagnostic test that can be distributed throughout the U.S., but it still could be a matter of weeks before it's ready.

*To view online:*

<https://subscriber.politicopro.com/health-care/whiteboard/2020/01/cdc-5-cases-of-wuhan-virus-confirmed-in-us-with-more-expected-3976001>

**You received this POLITICO Pro content because your customized settings include: FDA. To change your alert settings, please go to <https://subscriber.politicopro.com/settings>.**



This email alert has been sent for the exclusive use of POLITICO Pro subscriber, sh1@fda.hhs.gov. Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to [politicopro.com](http://politicopro.com).

---

This email was sent to sh1@fda.hhs.gov by:

POLITICO, LLC

1000 Wilson Blvd.

Arlington, VA 22209

USA ■

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/27/2020 4:55:05 PM  
**To:** Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]  
**CC:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbefee5ffeb7f3d-Heather.Jan]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]  
**Subject:** Re: TWEETS for REVIEW: Coronavirus - Monday Update

Thanks, Brad. Approved.  
Steve

---

**From:** "Kimberly, Brad" <Brad.Kimberly@fda.hhs.gov>  
**Date:** Monday, January 27, 2020 at 4:23 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Laura Caliguiri <Laura.Caliguiri@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Heidi Rebello <Heidi.Rebello@fda.hhs.gov>, "Janik, Heather" <Heather.Janik@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>, "Rabin, Tara G." <Tara.Rabin@fda.hhs.gov>, "Thorpe, Valarie" <Valarie.Thorpe@fda.hhs.gov>  
**Subject:** TWEETS for REVIEW: Coronavirus - Monday Update

Good afternoon... a thread for your quick review. Plan is to publish ASAP. Thanks! --Brad

===

### Coronavirus – MON PM

1. As part of @US\_FDA's vital mission to protect & promote public health, today, we are launching a new landing page that provides key #coronavirus information for the public, incl. product developers, on the FDA's efforts in response to this outbreak. [\[LINK TO PR\]](#)
2. #FDA is closely collaborating w/ domestic & international public health partners to mitigate the impact of this novel #coronavirus.
3. To help address this urgent public health situation, we're actively leveraging the breadth of the agency's expertise, & employing the full range of our public health authorities to facilitate the development/availability of investigational medical products

4. We're also sharing updates today on processes in place to help developers understand the pathways, including Emergency Use Authorization (EUA), that may be available to more rapidly advance & make medical countermeasures available for this virus, including diagnostic tests

5. FDA will continue to collaborate with interagency partners, product developers, international developers & global regulators to expedite the development/availability of medical products to diagnose, treat, mitigate & prevent such outbreaks. **[GRAPHIC]**

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-1002 | Cell: 240-750-9302  
[brad.kimberly@fda.hhs.gov](mailto:brad.kimberly@fda.hhs.gov)





---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/28/2020 7:23:17 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** COV Sitrep 1/28/2020  
**Attachments:** 04\_2019-nCoV Outbreak\_FDA SITREP\_28 January 2019.docx

Today's COV sitrep is attached. Sending directly o you since this is coming later in the day due to late breaking inputs.

Frank is copied to provide a hard copy tomorrow.

Internal confidential

**From:** Vinu Arumugham (b)(6)  
**Sent:** 1/28/2020 8:36:55 PM  
**To:** Slater, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2b00a57b0a747a9bc4f2317937a1022-slaterj]; Woo, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f70d0e3a7aaf442fb4962b61dde9894b-WooJ]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; CBER OCOD Consumer Account [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6d1fb37325043bcbe25183a0aaece3c-CBEROCOD]; DeStefano, Frank (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a799ec222e8741e988566e6141cbf1ba-HHS-fxd1-cd]; Thompson, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b2302812fa541759657b0569509577d-HHS-isq8-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Walker, Tanja Y (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ac93805a04cb2a742ec0845269e0f-HHS-hjn0-cd]; Secretary@HHS.gov; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; directorsincoming@cdc.gov; francis.collins (b)(6) mrolfes1@cdc.gov; Doyle, Joshua D (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6f540756f5e4fb28f6342abb37adc80-HHS-xzd2-cd]; Blanton, Lenee H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af6c9acc0f6462e9ec15ac743cdc7-HHS-acy9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Tumpey, Terrence M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21ce7e7681c44913862a0b4829d19df6-HHS-tft9-cd]; Wentworth, David E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c0bcb905b046c28f7e56cd5f2c54f5-HHS-gl19-cd]; sharplessne@nih.hhs.gov; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Kretsinger, Katrina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e123d287c55c449d84c4e5dcafb80a33-HHS-kok4-cd]; Linkins, Robert (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ac11517f634867818d7a8882a915a1-HHS-rxl3-cd]; Epperson, Scott (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884f3347a42048deb11c01980beccbc2-HHS-gbq7-cd]; Andes, Linda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f7897f96c74f229c4795e534d64f17-HHS-fwf7-cd]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcd41f240d7-Megan.McSev]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; rburke@cdc.gov  
**Subject:** Fwd: Wuhan 2019-nCoV: Reduce transmission, severity, by increasing indoor temperature

----- Forwarded Message -----

**Subject:** Wuhan 2019-nCoV: Reduce transmission, severity, by increasing indoor temperature

**Date:** Tue, 28 Jan 2020 13:54:59 -0800

**From:** Vinu Arumugham (b)(6)

**To:** dschui (b)(6) <dschui (b)(6)>, wpchnwr@who.int <wpchnwr@who.int>, wpchnmedia@who.int <wpchnmedia@who.int>, wprocom (b)(6) <wprocom (b)(6)>, mediainquiries (b)(6) <mediainquiries@who.int>, 13698665 (b)(6) <13698665 (b)(6)>, lifang (b)(6) <lifang (b)(6)>, LDu@nybc.org <LDu@nybc.org>, kyyuen (b)(6) <kyyuen (b)(6)>, mark.woolhouse (b)(6) <mark.woolhouse (b)(6)>, Christopher Whitty (b)(6) <Christopher.Whitty (b)(6)>, vimenach (b)(6) <vimenach (b)(6)>, jiwei yunlong (b)(6) <jiwei yunlong (b)(6)>, Jennifer.Layden@Illinois.gov <Jennifer.Layden@Illinois.gov>, caobin ben (b)(6) <caobin ben (b)(6)>, wangjw28 (b)(6) <wangjw28 (b)(6)>, hkmj@hkam.org.hk <hkmj@hkam.org.hk>, david.heyman (b)(6) <david.heyman (b)(6)>, buddy.creech@vumc.org <buddy.creech@vumc.org>, paul.cleary@phe.gov.uk <paul.cleary@phe.gov.uk>, legionella@phe.gov.uk <legionella@phe.gov.uk>, i.abubakar (b)(6) <i.abubakar (b)(6)>, theresa.lamagni@phe.gov.uk <theresa.lamagni@phe.gov.uk>, mainirishma (b)(6) <mainirishma (b)(6)>, hongxin.zhao@hpa.org.uk <hongxin.zhao@hpa.org.uk>, frances.parryford@phe.gov.uk <frances.parryford@phe.gov.uk>, david.ishola@hpa.org.uk <david.ishola@hpa.org.uk>, nick.phin@hpa.org.uk <nick.phin@hpa.org.uk>, katherine.henderson@hpa.org.uk <katherine.henderson@hpa.org.uk>, adrian.dix.MLA (b)(6) <adrian.dix.MLA (b)(6)>, bonnie.henry@gov.bc.ca <bonnie.henry@gov.bc.ca>, sahly (b)(6) <sahly (b)(6)>, deanmed (b)(6) <deanmed (b)(6)>, joewu (b)(6) <joewu (b)(6)>, lgralins (b)(6) <lgralins (b)(6)>

Increasing indoor temperature may be a relatively easy way to reduce transmission and reduce disease severity of 2019-nCoV infection.

Of course this is in general a good idea even for influenza/common cold virus transmission.

Thanks,

Vinu

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/29/2020 2:00:17 PM  
**To:** Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]  
**CC:** Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Wong, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d297edf2c28b4219a30b385f8dd3ab37-Eric.Wong]  
**Subject:** Re: Coronavirus Data Call

Thanks, Bill.  
Steve

---

**From:** "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Date:** Tuesday, January 28, 2020 at 5:34 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** James Tyler <James.Tyler@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, James Sigg <Jim.Sigg@fda.hhs.gov>, Angelique Hebert <Angelique.Hebert@fda.hhs.gov>, "Wong, Eric" <Eric.Wong@fda.hhs.gov>  
**Subject:** Coronavirus Data Call

Hi Dr. Hahn,

While we are not part of the formal data call from OMB, HHS asked us to identify our costs associated with the Coronavirus. Attached is the data we collected from across FDA. We captured costs to date as well as anticipated costs for the rest of FY 2020.

Let us know if you have any questions.

Thanks

Bill Tootle

*Director, Office of Budget  
U.S. Food and Drug Administration  
4041 Powder Mill Road,  
Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 1/29/2020 2:40:37 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Coronavirus Data Call

Thanks

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Wednesday, January 29, 2020 at 2:40 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Re: Coronavirus Data Call

Looks good. They got the info from the centers and offices. Think it's good to send. I will encourage the ASFR to send over to OMB too.

Sent from my iPhone

On Jan 29, 2020, at 2:00 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thoughts?

---

**From:** "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Date:** Tuesday, January 28, 2020 at 5:34 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** James Tyler <James.Tyler@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, James Sigg <Jim.Sigg@fda.hhs.gov>, Angelique Hebert <Angelique.Hebert@fda.hhs.gov>, "Wong, Eric" <Eric.Wong@fda.hhs.gov>  
**Subject:** Coronavirus Data Call

Hi Dr. Hahn,

While we are not part of the formal data call from OMB, HHS asked us to identify our costs associated with the Coronavirus. Attached is the data we collected from across FDA. We captured costs to date as well as anticipated costs for the rest of FY 2020.

Let us know if you have any questions.

Thanks

Bill Tootle

*Director, Office of Budget  
U.S. Food and Drug Administration  
4041 Powder Mill Road,  
Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

<FY 20 Coronavirus Outbreak Spending.xlsx>

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/29/2020 7:28:06 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** 1/29 COV Sitrep  
**Attachments:** 05\_2019-nCoV Outbreak\_FDA SITREP\_29 January 2019.docx

Attached.

Frank, please make sure a hard copy is available for the Commissioner tomorrow.

Thanks, all.

Internal confidential

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/30/2020 6:10:29 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** 30 Jan SITREP  
**Attachments:** 06\_2019-nCoV Outbreak\_FDA SITREP\_30 January 2019.docx

Attached please find today's COV sit rep. Thanks.

Internal confidential



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/31/2020 5:18:50 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** 1/31/20 COV Sit Rep  
**Attachments:** 07\_2019-nCoV Outbreak\_FDA SITREP\_31 January 2020.docx  
**Importance:** High

Today's sit rep is attached. Thanks.

Internal confidential pre decisional deliberative

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 1/31/2020 6:22:10 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbeyee5ffeb7f3d-Heather.Jan]; Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]  
**Subject:** RE: FDA nCoV Update 1/31

Colleagues

(b)(5)

(b)(5)

(b)(5)

As always, thank you for your collaboration in these important endeavors.

Internal confidential

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Sent:** Friday, January 31, 2020 5:45 PM

**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>

**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>

**Subject:** FDA nCoV Update 1/31

Dear colleagues,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn.

(b)(5)

Best regards,

*Denise*

RADM Denise M. Hinton  
U.S. Public Health Service  
Chief Scientist  
Food and Drug Administration  
Office (301) 796-1090

Internal, confidential

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 2/1/2020 8:14:46 AM  
**To:** Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**CC:** Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]  
**Subject:** RE: CDC Coronavirus Talking Points - 1/31/20

Thx Anna and Peter

---

**From:** Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Date:** February 1, 2020 at 7:54:58 AM EST  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Cc:** Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** RE: CDC Coronavirus Talking Points - 1/31/20

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/1/2020 2:47:39 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: Shortages  
**Attachments:** FDA ongoing supply chain activities.\_01 FEB 2020.docx

FYI in case helpful for today's 3 pm with AMA. (b)(5)

(b)(5)

Internal confidential

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Saturday, February 1, 2020 2:24 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** RE: Shortages

Hi – attached is info on FDA supply chain activities. Let me know if you have any Qs.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Saturday, February 1, 2020 10:50 AM  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** RE: Shortages

3 pm

Dr. Hahn will join call as well

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Date:** February 1, 2020 at 10:31:22 AM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** RE: Shortages

Will get u something. What time r u talking w/secretary?

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Saturday, February 1, 2020 9:39 AM  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** Shortages

Good morning (b)(5)

(b)(5)

Thanks!

Internal confidential

**From:** vinu arumugham; (b)(6)  
**Sent:** 2/2/2020 1:51:30 AM  
**To:** wiv@ (b)(6); suoban@ (b)(6)  
**CC:** dschul@ (b)(6); wpchnwr@ (b)(6); wpchnmedia@ (b)(6); wprocom@ (b)(6); mediainquiries@ (b)(6); 13698665@ (b)(6); lifang@ (b)(6); edu; LDu@ (b)(6); kyyuen@ (b)(6); mark.woolhouse@ (b)(6); Christopher.Whitty@ (b)(6); vimenach@ (b)(6); jiwei\_yunlong@ (b)(6); Jennifer.Layden@ (b)(6); caobin\_ben@ (b)(6); wangjw2@ (b)(6); hkm@ (b)(6); david.heyman@ (b)(6); buddy.creech@ (b)(6); paul.clear@ (b)(6); legionella@ (b)(6); i.abubakar@ (b)(6); theresa.lamagni@ (b)(6); mainirishma@ (b)(6); hongxin.zhao@ (b)(6); frances.parryford@ (b)(6); david.ishola@ (b)(6); nick.phin@ (b)(6); katherine.henderson@ (b)(6); adrian.dix.MLA@ (b)(6); bonnie.henry@ (b)(6); deanmed@ (b)(6); joewu@ (b)(6); lgralins@ (b)(6); maria.van-kerkhove@ (b)(6); Slater, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2b00a57b0a747a9bc4f2317937a1022-slaterj]; Woo, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f70d0e3a7aaf442fb4962b61dde9894b-WooJ]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; CBER OCOD Consumer Account [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6d1fb37325043bcbe25183a0aaece3c-CBEROCOD]; DeStefano, Frank (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a799ec222e8741e988566e6141cbf1ba-HHS-fxd1-cd]; Thompson, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b2302812fa541759657b0569509577d-HHS-isq8-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Walker, Tanja Y (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb1ac93805a04cb2a742ec0845269e0f-HHS-hjn0-cd]; Secretary@HHS.gov; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissioner]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; directorsincoming@cdc.gov; francis.collins@nih.gov; mrolfes1@cdc.gov; Doyle, Joshua D (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6f540756f5e4fb28f6342abb37adc80-HHS-xzd2-cd]; Blanton, Lenee H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af6c9acc0f6462e9ec15ac743cdcbc7-HHS-acy9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Tumpey, Terrence M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21ce7e7681c44913862a0b4829d19df6-HHS-tft9-cd]; Wentworth, David E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c0bcb905b046c28f7e56cd5f2c54f5-HHS-gl19-cd]; sharplessn@ (b)(6); Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Kretsinger, Katrina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e123d287c55c449d84c4e5dcafb80a33-HHS-kok4-cd]; Linkins, Robert (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ac11517f634867818d7a8882a915a1-HHS-rxl3-cd]; Epperson, Scott (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884f3347a42048deb11c01980beccbc2-HHS-gbq7-cd]; Andes, Linda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f7897f96c74f229c4795e534d64f17-HHS-fwf7-cd]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; rburke@cdc.gov

**Subject:** Shuanghuanglian for Wuhan 2019-nCoV treatment

Hi,  
I have been recommending antihistamines and mast cell stabilizers for Wuhan 2019-nCoV treatment (please see forwarded email below).

I read about your recommendation of Shuanghuanglian (SHL) for Wuhan 2019-nCoV treatment. It makes sense.

*Shuang-Huang-Lian Attenuates Airway Hyperresponsiveness and Inflammation in a Shrimp Protein-Induced Murine Asthma Model.*

<https://www.ncbi.nlm.nih.gov/pubmed/30713573>.

I read in the above article that SHL can act as a mast cell stabilizer so it is understandable that it will help in 2019-nCoV infection as detailed in my email below.

Thanks,  
Vinu

----- Forwarded Message -----

**Subject:** The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health - The latest 2019 novel coronavirus outbreak in Wuhan, China.

**Date:** Wed, 22 Jan 2020 20:32:52 -0800

**From:** vinu arumugham (b)(6)

**To:** dschui (b)(6) <dschui (b)(6)>, wpchnwi (b)(6) <wpchnwi (b)(6)>, wpchnmedia (b)(6) <wpchnmedia (b)(6)>, wprocom (b)(6) <wprocom (b)(6)>, mediainquiries (b)(6) <mediainquiries (b)(6)>, 13698665 (b)(6) <13698665 (b)(6)>, lifang (b)(6) <lifang (b)(6)>, LDu (b)(6) <LDu (b)(6)>

Dr. Hui,

IgE mediated sensitization to peptides that have homology to 2019-nCoV peptides may contribute to disease severity. In that case, antihistamines and other allergy treatments such as mast cell stabilizers may help reduce infection severity.

A BLASTP analysis of 2019-nCoV proteome against common vaccine antigens was performed. Preliminary results suggest that IgE mediated sensitization to common vaccine antigens can result in cross reactive immune responses to 2019-nCoV.

Please see details of the mechanisms here:

Influenza vaccines and dengue-like disease

<https://www.bmj.com/content/360/bmj.k1378/rr-15>

<https://www.guora.com/Why-was-the-flu-so-deadly-in-outbreaks-in-the-past-And-what-made-the-flu-become-less-deadly/answers/86456279>

Thanks,

Vinu



---

**From:** Russ, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2900752ACF81445785FB0F5B23C728C8-WRUSS]  
**Sent:** 2/3/2020 8:00:25 AM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** FW: FDA OEM/OEO Weekly Report for 01/31/2020  
**Attachments:** January 31, 2020 Weekly Report for FDA.pdf

Please share with Dr. Hahn.

---

**From:** Frasca, Dominic <Dominic.Frasca@fda.hhs.gov>

**Sent:** Friday, January 31, 2020 4:55 PM

**To:** Commissioner FDA <CommissionerFDA@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Slikker, William <William.Slikker@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Valdez, Mary Lou <MaryLou.Valdez@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Morrison, Ellen F <Ellen.Morrison@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Kux, Leslie <Leslie.Kux@fda.hhs.gov>; Dickinson, Elizabeth (FDA) <Elizabeth.Dickinson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

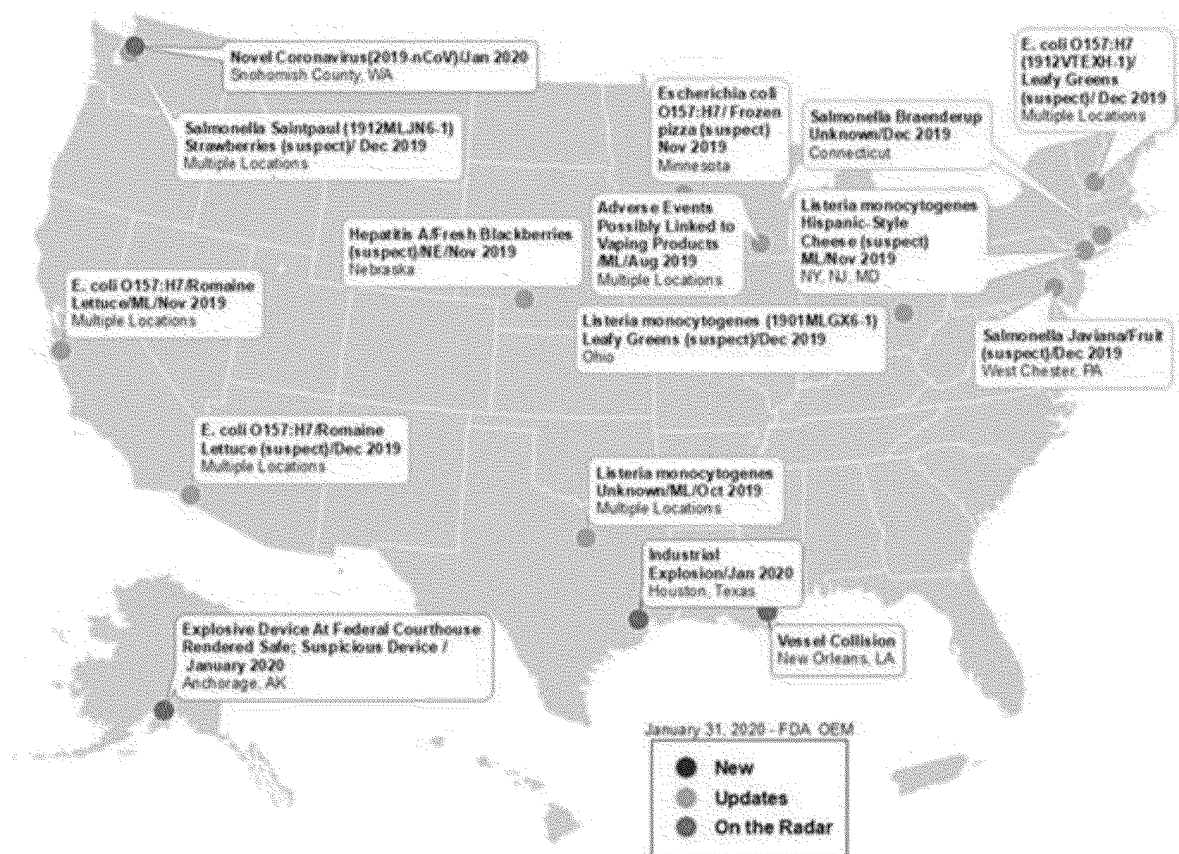
**Cc:** Russo, Mark <Mark.Russo@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CVM ECRS <CVMECRS@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; CFSAN-EC STAFF <CFSAN-ECSTAFF@fda.hhs.gov>; CORE Management Team <COREManagementTeam@fda.hhs.gov>; CORE Response <COREResponse@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Nelson, Eric <Eric.Nelson@fda.hhs.gov>; Welch, Jan <Jan.Welch@fda.hhs.gov>; Simoneau, Ann <Ann.Simoneau@fda.hhs.gov>; Correll, William A <William.Correll@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; GO-IO <GO-IO@fda.hhs.gov>; OC-OIP-OD-Directors <OCOIPOC@fda.hhs.gov>; ORA Recall OE <orarecalloe@fda.hhs.gov>; CFSAN-OC Mgmt <CFSAN-OCMgmt@fda.hhs.gov>; Taube, Anthony C <Anthony.Taube@fda.hhs.gov>; ORA RFDDs <orarafd@fda.hhs.gov>; ORA DDs <oradd@fda.hhs.gov>; ORA DIBs <orahqdibs@fda.hhs.gov>; OC OEA OMA-Press <OCOEAOA-Press@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Nelligan, Jeff <Jeff.Nelligan@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Crosby, Kathleen <Kathleen.Crosby@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>; Freedman, Elizabeth J <Elizabeth.Freedman@fda.hhs.gov>; CORE Communications <CORECommunications@fda.hhs.gov>; Hermsen, Catherine <Catherine.Hermsen@fda.hhs.gov>; Strucker, Ray <Raymond.Strucker@fda.hhs.gov>; Musser, Michael <Michael.Musser@fda.hhs.gov>; Priest, Deborah <Deborah.Priest@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Serrano, Katherine M <Katherine.Serrano@fda.hhs.gov>; Rodriguez, Michelle <Michelle.Rodriguez@fda.hhs.gov>; Cochran, Chrissy <Chrissy.Cochran@fda.hhs.gov>; ORA Emergency Response Coordinators <ORAEmergencyResponseCoordinators@fda.hhs.gov>; Howard King, Vinetta <Vinetta.HowardKing@fda.hhs.gov>; Norris, Paul E. <Paul.Norris@fda.hhs.gov>; Stromgren, Selen <Selen.Stromgren@fda.hhs.gov>; McGrath, Timothy <Timothy.McGrath@fda.hhs.gov>; Ruisanchez, Kristina <Kristina.Ruisanchez@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; ElZarrad, M.

Khair <Mohammed.ElZarrad@fda.hhs.gov>; Budashewitz, Philip <Philip.Budashewitz@fda.hhs.gov>; Concato, John <John.Concato@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Harmon Jr, Lawrence <Lawrence.Harmon@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Smith, Crystal <Crystal.Smith@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>

**Subject:** FDA OEM/OEO Weekly Report for 01/31/2020

## FDA OFFICE OF EMERGENCY MANAGEMENT WEEKLY REPORT – January 31, 2020

*This document is confidential and is only for internal FDA use for emergency operations purposes. This document contains non-public information and may include information for which public disclosure is prohibited by law (such as confidential commercial information, trade secret, and personal privacy information) and information compiled for enforcement purposes. This document was prepared by FDA's Office of Emergency Management (OEM)/Office of Emergency Operations (OEO). Any request to distribute this information outside of FDA must be approved by OEM.*



### UPDATES

**Adverse Events Possibly Linked to Vaping Products/Unknown/ML/Aug 2019,**

Since August 2019, FDA has been working with the Centers for Disease Control and Prevention (CDC) and state/local public health partners to investigate a multistate outbreak of severe pulmonary illness/injury, which the CDC has labeled EVALI (e-cigarette, or vaping, product use associated lung injury). As of **1/21/2020**, CDC reports a total of **2,711** hospitalized cases of EVALI have been reported from all 50 states, the District of Columbia, and two U.S. territories (Puerto Rico and U.S. Virgin Islands); **60** deaths have been confirmed in 27 states and the District of Columbia. According to the CDC, all reported case patients have a history of vaping product use. The CDC also reports that most patients have a history of using vaping products containing THC (tetrahydrocannabinol), many have reported using THC and nicotine, and some have reported the use of vaping products containing only nicotine. Overall, according to CDC, 152 different THC-containing product brands were reported by EVALI patients. The CDC has reported that although public health partners have made progress in identifying substances of concern in EVALI, there are many different substances and product sources that remain under investigation, and there may be more than one cause. The CDC provides updates for this investigation, including count updates, on its website [CDC web page link](#).

The FDA Incident Management Group (IMG), activated on 9/6/2019, continues to coordinate FDA's activities for the investigation of pulmonary illness/injury incidents related to the use of vape products. The IMG is comprised of FDA staff from the Office of Emergency Management (OEM), Center for Tobacco Products (CTP), Center for Drug Evaluation and Research (CDER), Office of Regulatory Affairs (ORA), Office of Media Affairs (OMA), Office of Chief Counsel (OCC), Office of Legislation (OL), and Office of Intergovernmental Affairs (IGA). An FDA Agency Executive Group (AEG), also activated on 9/6/2019, comprised of senior Agency staff, is provided with weekly situational updates and present high-level policy decisions that need to be addressed. FDA is analyzing product samples submitted by states for the presence of a broad range of chemicals, including nicotine, THC and other cannabinoids, along with cutting agents/diluents and other additives, pesticides, opioids, poisons, heavy metals and toxins. As of **1/29/2020**, FDA has received over 1,300 samples from 31 states and one territory. At this time FDA has not found one product or substance that is involved in all of the cases; however, THC is present in most of the samples tested. ORA continues to communicate with state partners regarding vape product sample results. The information below is from the most recent FCC laboratory report, **1/29/2020**:

#### Sample Analysis:

- Approximately 1070 samples are connected to patients.
- Approximately 289 samples are investigative samples that are not connected to patients.
- To date, product samples linked to **89** patient cases have been analyzed:
  - **42 of 89** are linked to nicotine products
  - **66 of 89** are linked to THC products
  - **53 of 89** are linked to THC containing vitamin E acetate (VEA)
  - **6 of 89** are linked to THC products containing polyethylene glycol
  - **17 of 89** are linked to THC products with no other major diluent identified
  - **22 of 89** are linked to THC products containing aliphatic esters as diluent (e.g., triglycerides)

The IMG Public Affairs Specialists continue to consult with CDC's communications group to provide a coordinated approach to public messaging. An FDA public webpage [FDA web page link](#) provides updates on the investigation and preliminary laboratory testing results.

**In a 1/24/2020 CDC Morbidity and Mortality Weekly Report (MMWR) link to MMWR, researchers reported most patients with EVALI report using THC-containing products, however, some report using only nicotine-containing products. According to the report, among 121 interviewed Illinois EVALI**

patients, nine who reported using only nicotine-containing products and had no indication of any THC use were more likely to be older, female, and less likely to experience constitutional symptoms or leukocytosis than were patients who used THC-containing products. The report further stated that although VEA has been strongly linked with EVALI, evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC- or non-THC-containing products, in some reported EVALI cases. In another recent CDC MMWR [link to MMWR](#), researchers stated the number of EVALI cases reported to CDC peaked during the week of 9/15/2019 and the weekly number of hospitalized patients has since steadily declined. The report further advised clinicians and public health practitioners to remain vigilant for EVALI cases. OEO will continue to report.

***Listeria monocytogenes* (1702MLGX6-1)/Unknown/Oct 2019**

CORE and CDC are continuing to evaluate a persistent strain of *Listeria monocytogenes* associated with cluster 1702MLGX6-1. This cluster was previously investigated in 2017 and 2018, but no vehicle was confirmed during the outbreak response. CDC closed the cluster investigation in early 2019 and since then new clinical matches with this strain have been identified. On 11/12/2019, CDC formally re-opened the investigation for this cluster. Isolation dates range from 9/16/2011 - 9/04/2019. All isolates in the cluster are highly related by WGS (within 0-18 alleles, median 4 alleles), including clinical isolates and several U.S. potato isolates tested by SENASICA, a focus of last year's investigation. Currently, no suspect vehicle has been identified.

Case-patients have been interviewed using several approaches including the *Listeria* Initiative questionnaire, open-ended interviews, and two different supplemental questionnaires including questions about processed frozen foods and potato products. Many cases have reported lower-cost foods and frozen foods, including frozen meals and frozen snack foods, as well as fresh, frozen, and refrigerated potato products, although no specific brand or food item is standing out. A majority of cases (26/40 (65%) with grocery store information available have reported a national grocery chain in common. On 11/14/2019, OAO/Biostatistics & Bioformatics Branch provided an updated WGS analysis showing that the seven SENASICA potato isolates are genetically identical to 57 clinical isolates in the database at 0-20 SNPs with a median of 5 SNPs. FDA has received information about a state's investigation of this cluster and FDA has requested manufacturer information for specific products case patients reported purchasing.

(b)(5)

(b)(5)

CORE will only

report should a significant development in the investigation occur.

**Hepatitis A/Fresh Blackberries (suspect)/Nov 2019**

On 11/06/2019, CORE Signals was notified about a cluster of 5 Hepatitis A illnesses in Nebraska (NE). By 11/13/2019, the number of cases had increased to 6 cases in NE and 2 cases in Indiana. NE and IN are not otherwise experiencing an outbreak of Hepatitis A. All eight cases have purchased fresh blackberries from four different locations of the same chain of grocery store. Douglas County Health Department (Omaha, NE) is collecting receipts and traceability information for the blackberries.

On 11/15/2019, HAF 6E (CHI) facilitated an FDA and CDC call with a firm of interest, Fresh Thyme, to discuss the current outbreak. The firm is working to gather traceback records for FDA. HAF 6E (CHI) provided Fresh Thyme records for fresh blackberries from a single store in IN and fresh strawberries for stores in NE and

a single store in IN. On 11/18/2019, CDC Viral Hepatitis Branch held a call with the 11 states that have Fresh Thyme locations to discuss the outbreak, call for cases, and discuss communications plans; CORE represented FDA on this call.

On 11/20/2019, FDA and CDC published web advisories regarding fresh blackberries purchased from Fresh Thyme Farmers Market grocery stores:

- FDA: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-hepatitis-potentially-linked-fresh-conventional-blackberries-fresh-thyme>
- CDC: <https://www.cdc.gov/hepatitis/outbreaks/2019/hav-berries/index.htm>

The traceback investigation continues and assignments have been issued for record and possible sample collection at blackberry and strawberry suppliers to the Fresh Thyme distribution center. Product samples, including a sample in import status from Mexico, have tested negative for Hepatitis A. Additional sample collection and analysis are ongoing. FDA has also increased import screening for a firm of interest. On 12/6/2019, CORE sent a Binational Protocol outbreak notification to LAO to share with Mexico's government officials and LAO sent the notification of the outbreak to Mexico's officials, SENASICA and COREPRIS. There are currently 18 cases in this outbreak, IN (2), MI (1), MN (1), MO (1), NE (7), WI (6). FDA and CDC updated the web posts with case counts and epi information.

On 12/30/2019, HAF2W (KAN) provided records collected from Proffer Wholesale Produce, Inc., Park Hills, MO. Proffer supplied fresh blackberries to a Woodman's Market point of service during the period of interest. On 12/31/2019, CDC reported two new cases, in PA and WI identified through sequencing. Epidemiologic investigations on the two are ongoing. PHI-DO and the PA DOH are following up on PA case's shopper card history at Giant Eagle, Slippery Rock PA. On 1/2/2020, ORA's Division of Southwest Imports (DSWI) provided more traceback records for TransKool Solutions, McAllen, TX. On 1/9/2020, FDA Office of Emergency Management provided a map of firms from Mexico identified in the fresh blackberries traceback. On 1/22/2020, FDA held a conference call with Mexican health authorities to discuss the outbreak and solicit additional information.

**On 1/29/2020, CORE requested that HAF 3W (DAL) obtain information on the source of fresh blackberries supplied between 10/23/2019 and 11/27/2019 to a Walmart in Arizona and between 9/23/2019 and 10/28/2019 to another Walmart in Pennsylvania. Each facility was reported as the purchase location by recent hepatitis A cases. HAF 3W is following up with Walmart headquarters. CORE will continue to coordinate.**

#### ***Salmonella* Javiana/Fruit (suspect)/Dec 2019.**

On 12/4/2019, CORE learned from an Epi-X notification about multiple outbreaks of *Salmonella* infections among patients who were exposed to healthcare facilities. There were 29 cases reported in 2 hospital and 2 long term care facilities in PA; some cases had been identified as *Salmonella* Javiana (WGS pending) and others were still pending additional characterization. Interviews conducted at one hospital indicate that 89% (8/9) cases reported eating "fruit cups" at least once and 44% (4/9 + 1 "maybe") report eating various forms of chicken. The fruit cup is produced by a firm in NJ that distributes regionally to nearby states, including PA. Food samples were collected for testing. On 12/6/2019, a states call was held to discuss the incident and FDA and PA issued public communications regarding this incident. Tailor Cut Produce, a firm of interest, issued a *recall* of product.

On 12/6/2019, HAF 2E (PHI) provided records for health care facilities that received cut fruit from US Foods. During a CDC-hosted call on 12/9/2019, PA DoH indicated serotyping for one case from one of the four health care facilities in PA has a non-Javiana serotype. The facility did not receive product from the firm of interest, Tailor Cut Produce. States reported three other *Salmonella* Javiana clusters potentially linked to this outbreak, one in DE and two in New York City (one associated with a conference at the Intercontinental Hotel 11/19/2019-11/20/2019 and the other associated with New York University). Sequencing information from 10 cases in PA and one case tested in MN match with 0 allele differences. The MN case attended the conference at the Intercontinental Hotel in NYC. On 12/9/2019, purchase records were provided by HAF 2E (NWJ) from Tailor Cut Produce. On 12/9/2019, HAF 1E (NYK) provided traceback documents from NYU-Kimmel Market Place and the Intercontinental Hotel. On 12/9/2019, CDC reported that cluster 1912PAJGG-1 was assigned to this outbreak. On 12/9/2019, CORE issued an assignment for HAF 2E (NWJ) for a Preventative Controls (PC) inspection with environmental sampling and traceback record collection at Tailor Cut Produce Inc. and this inspection was initiated 12/10/2019. The Arkansas Lab was identified to service sample for this investigation.

On 12/11/2019, an assignment was issued to HAF 2E (NWJ) for record and possible sampling at US Foods in Swedesboro, NJ. On 12/11/2019, an assignment was issued to HAF 2E (NWJ) for record and possible sampling at Riviera Produce in Englewood, NJ. On 12/11/2019, public communications were updated:

- FDA: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-salmonella-potentially-linked-tailor-cut-produce-fruit-mix-winter-2019>
- CDC: <https://www.cdc.gov/salmonella/javiana-12-19/index.html>

On 12/12/2019, CDC hosted a States call. On this call, DE indicated that their cases are linked via traceback to Tailor Cut produce through the distributor American Beauty & Fish. WGS is pending for DE cases. Also discussed was a new case identified though WGS from VA. HAF 2E (PHI) provided records from DE Division of Public Health related to cases associated with two school districts. The single case from DE in the line list is an attendee of one of these school districts.

HAF 2E (NWJ) shared preliminary information regarding the ongoing inspection. CORE added a request for the complete list of products prepared by Tailor Cut Produce. On 12/12/2019, HAF 2E (NWJ) initiated an inspectional assignment at Riviera Produce in North Brunswick, NJ and an inspectional assignment at US Foods in Swedesboro, NJ (records are located at Bridgeport, NJ location). CORE will continue to coordinate. On 12/19/2019, CDC held a states call where VA reported that their case had travel associated to PA. The incident currently has 96 (+4) cases. Onset Date Range: 11/15/2019 – 12/1/2019.

On 12/30/2019, HAF 2E (PHI) provided records collected by PA Department of Agriculture for the Sonesta Hotel in Malvern, PA and the Fairfield Inn in Broomall, PA. On 12/31/2019, HAF 1E (NYK) sent records for D'Arrigo Bros. Co. of New York, Inc. On 12/31/2019 reported initiating an assignment at First Choice Food Distributors (Philadelphia, PA). A cantaloupe sample consisting of 10 subs was collected and shipped to ORA's Arkansas Laboratory (ARKL) for testing.

On 1/2/2020, FDA and CDC issued public communications updating case counts. Also on 1/2/2020, CDC sent records to CORE from the Hampton Inn, Glen Mills, PA. On 1/8/2020, HAF 2E (NWJ) sent records to CORE from Guarino and Sons, Inc., National Park, NJ (FEI: 3003466234). On 1/9/2020, CDC identified a new cluster associated with Shop Rite stores in NJ. This includes eight cases from three Shop Rite stores. NJ Department of Health is working to obtain shopper card records and for some of these cases. On 1/16/2020, CFSAN OC,

OFS, and CORE met to discuss possible next steps at Tailor Cut Produce. On 1/16/2020, CORE received records from DSWI (Nogales) from produce house and Produce House (Nogales, AZ). On 1/17/2020, HAF 2E (PHI) provided additional information regarding First Choice (Philadelphia, PA), a supplier to Tailor Cut Produce. On 1/21/2020, HAF 2E (PHI) provided invoices from First Choice Distributors (Philadelphia, PA). On 1/22/2020, CORE received invoices through CDC from NJ Department of Health documenting orders for Southern Ocean Medical Center and Inspira Medical Center from Seashore Fruit and Produce, Inc (Vineland, NJ). This firm is a documented distributor for Tailor Cut Produce. On 1/23/2020, DSWI supplied trace forward information for cantaloupes imported by Produce House (Nogales, AZ). On 1/23/2020, CORE and CDC were invited by OC to provide traceback and epidemiology expertise during compliance discussions with Tailor Cut Produce. On 1/23/2020, CDC informed CORE that NJ Department of Health had communicated with Wakefern regarding cleaning practices at Shop Rite stores that received recalled product from Tailor Cut Produce.

**On 1/30/2020, CORE requested the collection of one sample of butternut squash from Juan Antonio Castelo de la Rosa (FEI: 3010202142) for Salmonella testing. Tailor Cut Produce was supplied cantaloupes from Juan Antonio Castelo de la Rosa and these cantaloupes were used on 11/14-11/18/2019. This time period is associated with production of large amount of cut fruit that is suspected to have caused most illnesses. Juan Antonio Castelo de la Rosa is only exporting butternut squash currently. CORE will continue to coordinate.**

#### **Salmonella Braenderup/Unknown/Dec 2019**

On 12/30/2019, CORE Signals was notified by CDC of a *Salmonella* Braenderup cluster (1912MLJBP-1) with a signal for meals at a national Mexican-style fast food chain. CDC/PulseNet reports 22 cases from 6 states: CT(7), MD(6), NH(1), NY(3), PA (3), and VA(2) with isolation dates ranging from 11/19/2019 to 12/5/2019. Ages range from 11 – 65 years (median: 40), and 70% of cases are female. Isolates are highly related by WGS (within 0-2 alleles). To date, 9/10 patients reported eating at the Mexican-style fast food chain prior to illness onset, and a sub-cluster location visited by 3 patients in CT has been identified. CDC is requesting additional information from state partners about the restaurant exposures, including meal items/dates and restaurant locations, and a focused-questionnaire is being deployed. Fresh produce items including lettuce and tomatoes are of interest. A CDC-hosted Multistate Call was held on 1/2/2020. CT partners have collected invoices and food ingredient samples at a POS location.

On 1/6/2020, a Firm Call was held with Taco Bell, Yum Brands, FDA and CDC to provide the firm with the most recent epi information and request traceback information. On 1/7/2020, HAF 5W (LOS) shared additional case exposure information with Taco Bell. On 1/8/2020, a Firm Call was held with Taco Bell, Yum Brands, FDA and CDC to provide the firm with the most recent epi information and request traceback information. Taco Bell provided traceback information for diced tomatoes and shredded iceberg lettuce. Representatives from Ready Pac (Florence, NJ), manufacturer of the iceberg lettuce, and Lipman Produce (Immokalee, FL), manufacturer of the tomatoes, were also on the call.

On 1/8/2020, the incident was transferred to CORE Response Team 1. On 1/9/2020, LOS-DO requested additional traceback information from Taco Bell. On 1/14/2020, FDA requested GPS coordinates and maps of Lipman tomato and Bengard lettuce farms harvested during the timeframe of interest. On 1/15/2020, Taco Bell provided lot numbers and harvest dates for lettuce and tomato shipments identified in traceback. On 1/15/2020, Taco Bell provided lot numbers and harvest dates for lettuce and tomato shipments identified in traceback. On

1/17/2020, Taco Bell provided additional information for tomato shipments identified in traceback, including harvest locations.

**On 1/30/2020, CORE issued an assignment to ORA PSN for a farm investigation, to include sampling, at Lipman Produce Farm 15, located in Immokalee, FL. Also, on 1/30/2020, CORE issued an assignment to ORA HAF 2E (NWJ) for an inspection, to include sampling, at The Thomas Colace Company located in West Deptford, NJ. CORE will continue to coordinate.**

***E. coli* O157:H7/Romaine Lettuce/ML/Nov 2019**

On 8/08/2019, CORE team was notified of a new *Enterohemorrhagic Escherichia coli* (EHEC) serotype O157:H7 (*E. coli* O157:H7) cluster of 5 cases (cluster code 1911MLEXH-1) matching a strain previously linked to leafy greens. This particular strain has previously caused multiple outbreaks linked to leafy greens, including the romaine outbreak in the fall of 2018 traced to multiple farms in the Santa Maria, CA region. CDC has indicated that no suspect vehicle has been identified yet for the current cluster, and the epidemiologic investigation is in progress. State public health partners are continuing to collect exposure information. All cases' *E. coli* O157:H7 are highly related by whole genome sequencing (WGS) and there is one recent matching Canadian case (within 0-1 alleles). During the 2018 outbreak investigation FDA, in collaboration with CDC and CA partners, conducted investigations at farms identified in the traceback; sampling yielded this strain in a positive environmental sample from sediment collected from an on-farm reservoir at a ranch in the Santa Maria region.

On 11/13/2019, FDA, together with CDC and CA state partners, initiated the investigation at Adam Bros Farming Inc. in Santa Maria, CA; updates provided by the investigational team noted that use of the reservoir at Ranch 10 had ceased; romaine was last harvested from Ranch 10 in mid-August and this ranch is currently planted with cauliflower and broccoli. Romaine was last harvest from Ranch 19 on 9/17/2019 and the firm reported this ranch is currently fallow. The investigational team collected drag swabs, soil, scat, and broccoli samples, which were sent overnight to FDA Pacific Southwest Food & Feed Laboratory (PSFFL) for analysis; CDC also sampled water and sediment on Ranch 10 and Ranch 17. On 11/14/2019, the investigational team at Adam Bros Farming Inc. collected additional drag swabs, soil and romaine samples, which were sent overnight to PSFFL for analysis. The investigation at Adam Bros was closed on 11/14/2019 pending sample results. On 11/17/2019, PSFFL reported that all 10 FDA samples collected from Adam Bros. were negative for EHEC.

FDA, along with public health partners, continue to conduct investigations at firms of interest and collect samples and distribution information. FDA is collecting and reviewing records to support a traceback investigation. FDA and CDC have issued public web posts about the ongoing investigation that includes, case count information, sample analytical results and consumer warnings. FDA is also investigating two additional *E. coli* O157:H7 outbreaks of less than a dozen cases each in multiple states who became ill from eating produce but were not infected by the same strain as this larger outbreak. The first outbreak involves eleven cases in WA state and the second separate outbreak includes ten cases in WI, IL, MN and ND (these incidents, # 2 and # 3 are discussed below).

Five FDA samples are under CFSAN review (including soil samples collected from Fresh Farms/South County Packing Breschini Ranch). 1 sub of sample 1095174 (soil) stx1 positive; WGS is pending. State samples: 1 positive; WGS match (romaine lettuce from an intact Ready Pac brand Chicken Caesar Salad collected by MD investigators) and 1 positive; WGS match (Leafy Green romaine Fresh Express brand collected by WI



investigators). CDC samples: 2 positives; WGS match (cow manure and water/sediment sample associated with Sisquoc Ranch/Winery; Santa Maria, CA).

On 1/3/2020, FLA-DO provided contract harvesting information obtained from Fresh Express Corporate associated with growers of interest. On 1/12/2020, CFSAN reported that the isolate recovered by ORA/ORS from sub 2 of sample 1905174 was unique to NCBI; this isolate was determined to be stx1d positive, with no other virulence genes present. Based on this information, the STEC Council felt it represented a 'low risk' to human health.

This outbreak has ended. On 1/15/2020, FDA and CDC issued final webposts for the outbreak investigation; an updated statement from the Deputy Commissioner for Food Policy and Response related to the closure of the 3 leafy green associated *E. coli* O157:H7 was also issued. **There will be no further reporting on this outbreak.**

#### ***E. coli* O157:H7/Romaine Lettuce (suspect)/Dec 2019**

On 12/20/2019, FDA was notified by CDC about *E. coli* O157:H7 cluster 1912NCEXH-1 with a signal for eating at a specific sandwich chain. The cluster consists of 19 cases across 8 states. Isolation dates range from 11/28/2019 to 12/6/2019. Ages range from 1 to 83 years (median 30). Fifteen (83%) of the cases are female. All isolates are highly related within 0 to 1 allele and 0 to 3 (median 1) SNPs. Nine cases have reported eating at multiple locations of a national sandwich chain. Fourteen of fifteen cases (including maybes) have reported exposure to iceberg, and 14/14 cases (including maybes) have reported exposure to romaine. CDC hosted a States call on 12/23/2019 to discuss the investigation. State investigators agreed to re-interview some cases with a modified questionnaire, which includes additional leafy green questions, and collect additional information including meal dates and meal records for cases reporting consuming products from the national sandwich chain.

HAF2W provided records from Panera pertaining to suppliers (growing region, GPS coordinates, farms, ranches, lots) that supplied romaine to Panera Point of Sales of interest. Issued HAF5E an assignment (MARCS #145302) to collect records from Freshway Foods pertaining to shipments, growers, ranches, and lots that supplied romaine to Panera. On 1/17/2020, FDA Office of Emergency Management provided a GIS map to common growers and ranches implicated with the multiple romaine outbreak traceback (Panera, National, and Sunflower Crisp Salad). HAF5E provided documents from Freshway to identify shipments, growers, ranches, and lots that supplied romaine to Panera (assignment MARCS #145302). **No updates.** CORE will continue to coordinate.

#### ***E. coli* O157:H7 (1912VTEXH-1)/Iceberg Lettuce (suspect)/Dec 2019**

On 12/18/2019, FDA was notified by CDC about *E. coli* O157:H7 cluster 1912VTEXH-1 with a signal for eating at a specific sandwich chain. The cluster consists of 11 cases across 4 states. Isolation dates range from 11/22/2019 to 12/05/2019. Ages range from 3 to 41 years (median 12). Six (55%) of the cases are female. All isolates are highly related within 0 to 5 (mean 1) SNPs. CDC hosted a States call on 12/19/2019 to discuss this incident. Nine of ten cases have reported eating at multiple locations of a national sandwich chain in VT, NH, and ME. Among these cases with exposure to the national chain, eight report eating foods that contained iceberg lettuce. VT collected lettuce samples from three locations, but all samples returned negative. On 12/19/2019, CDC indicated that iceberg lettuce is the suspect vehicle for the outbreak. State partners have initiated traceback activities, and additional information will be requested during a FDA/CDC call with the firm on 12/20/19. FDA and CDC held a Firm Call with the national sandwich chain's corporate office on 12/20/2019

and requested traceback information for iceberg lettuce. Supplier information from the firm was received and is being reviewed. This incident will be transferred from CORE Signals to CORE Response Team 3 today, 1/7/2020, for further coordination.

On 1/7/2020, this incident was transferred to CORE Response Team 3 for further coordination. On 1/7/2020, ORA HAF1E (NWE-DO) provided traceback information and records for this outbreak. Harris Farms (Coalinga, CA) identified as the source of the iceberg lettuce consumed by the cases. On 1/15/2020, ORA HAF 1E and HAF 5W provided farm level information for Harris Farms. On 1/22/2020, ORA HAF 5W (SAN-DO) reached out to Harris Farms to provide an epi summary from CDC and ask questions about the company. Harris Farms stated that the ranches identified in traceback are currently fallow and that the cattle operation was sold in April 2019.

On 1/24/2020, CORE issued FACTS Assignment #11987035 to ORA PSN for a farm investigation at Harris Farms (Coalinga, CA). A Special Purpose Tactics Call was held 1/24/2020 discussing the upcoming farm investigation at Harris Farms.

**From 1/28/2020 through 1/31/2020, provided updates on the farm investigation at Harris Farms. Soil, drag swabs, and one scat sample were collected, ss were sediment and scat samples. The team reviewed the farm's personnel training, health and hygiene training, surface water treatment procedures and BSAAO use. BSAAO was not applied to the implicated ranches. Evidence of wildlife activity was observed on all three ranches. ORA PSN and CDC Water team are tentatively scheduled to return to Harris Farms the week of 2/10/20 for CDC water sampling. The team met with representatives from and gained access to Harris Ranch Feeding Company. The team received a brief overview of the operation; the ranch is undecided about sampling. The Harris Farms investigation team will tentatively meet with Harris Fresh (cooler operation associated with Harris Farms) on 2/4/20 to learn about the cooling process; Harris Fresh is currently not in operation. On 1/30/20, ORA/ORS (Denver Laboratory) reported 4 environmental samples from Harris Farms are CRO for EHEC/STEC. Due to inhibition noted in the PCR screening, all subs are being plated for either confirmation testing or rule out. CORE will continue to coordinate.**

#### ***Listeria monocytogenes/Hispanic-Style Cheese (suspect)/Nov 2019***

On 11/22/2019, PulseNet assigned cluster code 1911MLGX6-1 to a *Listeria monocytogenes* cluster which includes 4 clinical isolates, and 3 environmental/product isolates associated with a NY cheese manufacturing facility. Investigational partners have collaborated to evaluate this retrospective cluster since 2018, as new matching cases were identified over a period of two years. The cluster currently includes 4 cases from 3 states, with isolation dates ranging from 3/02/2018 to 10/20/2019. Three cases are pregnancy associated, and one pregnancy ended in fetal loss. The sequencing analysis indicates the clinical and environmental/product isolates are highly related within 0-7 alleles (median=4 alleles).

Exposure information is available for 2 of the 4 cases; one 2018 NYC case and the 2019 NJ case both report the same brand of Hispanic-style cheese produced by a NJ firm. Cases have not reported the types of artisanal cheeses produced by a NY creamery with the matching environmental/product isolates. CDC indicates that Hispanic-style cheese is the suspect vehicle for this cluster. Investigational partners are collaborating to discuss

inspections at the cheese manufacturing facilities in NJ and NY. An assignment for a preventive controls inspection at El Abuelito (Paterson, NJ) has been issued.

On 1/6/2020, FDA HAF1E initiated the inspection at 5 Spoke Creamery (Goshen, NY). One environmental sample (#1123566) was collected. This sample was negative for *Listeria*. HAF2E initiated the inspection at El Abuelito (Paterson, NJ) on 1/14/2020 with one environmental sample (#1123037), consisting of 40 subs, collected on 1/15/2020. On 1/21/20, HAF2E collected two product samples (Sample# 1123038 and 1123039) from El Abuelito (Paterson, NJ). The samples were of Oaxaca and Queso Fresco; **results were negative**. On 1/23/2020, ORA/ORS reported that *Listeria grayi* was detected in sub 37 and *Listeria innocua* was detected in sub 40 of Sample #1123037. **On 1/29/20, HAF2E collected Sample #1123040, consisting of 50 swabs, from El Abuelito (Paterson, NJ).** CORE will continue to coordinate.

### **Salmonella Saintpaul (1912MLJN6-1)/Strawberries (suspect)/ Dec 2019**

On 12/7/2019 CORE Signals was notified by a PulseNet notification about a cluster of 10 cases of Salmonella Saintpaul that were highly related within 0-1 alleles. At the time of transfer, this cluster includes 76 cases from DC (1), IA (1), IL (17), IN(1), KS (4), MD (17), MI (1), MN (2), NE (7), NJ (1), NY (2), PA (1), VA (11), and WI (10). Cases are clustering in the upper east quadrant of the country. Isolation dates range from 11/13/2019 to 12/13/2019, and onset dates range from 11/7/2019 to 11/30/2019. 13 cases (24%) have been hospitalized and there are no deaths. Ages range from 1 to 83 years (median: 21), and 62% of cases are female. 72 of the isolates have been sequenced, submitted to the NIH National Center for Biotechnology Information (NCBI) database, and are related within 0-4 SNPs (average: 1).

On 12/11/2019, CDC hosted the first multi-state call for this incident and identified chicken (mainly rotisserie), various types of fruits, frozen vegetables, and tofu to be items of interest for this cluster and noted that many cases shopped at Costco. CDC also noted that the speed in which cases were being identified for this incident indicated a fresh, not frozen, food vehicle. A second multi-state call was held on 12/18/2019, and CDC identified fresh strawberries purchased from Costco to be a leading hypothesis for this outbreak. 7/12 cases reported fresh whole strawberries in 2 lb. clamshells and additional cases reported eating fresh cut strawberries from mixed fruit bowls, increasing the number of cases reporting fresh strawberries to 12/14 cases (86%).

A firm call was organized for 12/19/2019 to share information with Costco about the incident and to gather traceback information on strawberries and mixed fruit bowls. ORA HAF5W (Seattle District Office) collected records from Costco. Preliminary review of records indicated that most whole strawberries were sourced from CA, but some were sourced from Mexico. Due to the geographic clustering of cases in the upper east quadrant of the U.S., Costco hypothesized that there may be 2 distribution centers of the strawberries. On the call, Costco shared they purchase the cut mixed fruit bowls from an outside source and do not cut the fruit themselves. A review of records show that Costco mixed fruit bowls are sourced from 2 suppliers: Del Monte and Safeway Foods. Mixed fruit bowls from Safeway Foods (Vineland, NJ) contained strawberries during the timeframe of interest, and Del Monte mixed fruit bowls did not. Costco also noted that the only other product sold that contains fresh strawberries would be an acai bowl that is sold in the food court. As the food court uses separate registers than the grocery section, it is unlikely the purchase of the acai bowl would be shown on a shopper card. CDC noted they would modify their supplemental questionnaire to ask about acai bowls.

Review of records obtained thus far are under review to identify cases for which tracebacks should be conducted. On 1/8/2020 a request for clarification on information/documents provided by Costco was sent to

HAFW6 (SEA-DO). On 1/14/2020 RT4 issued an assignment to HAF2E for an investigation at Safeway Fresh Foods, Vineland, NJ, for the collection of records relating to the receipt of fresh strawberries and the distribution of fresh fruit bowls containing strawberries, as well as information on the firm practices. **On 1/30/2020, RT4 issued an assignment for an investigation and record collection at Naturipe Farms (Estero, FL), the supplier of fresh strawberries to Safeway Fresh Foods (Vineland, NJ) during the timeframe of interest.** CORE will continue to coordinate this investigation.

#### ***Escherichia coli* O157:H7/Frozen pizza (suspect)/Nov 2019**

FDA was notified by MIN-DO about a cluster of cases who reported consuming frozen pepperoni and/or sausage pizzas. There are 20 cases from 3 states: MN (18), IL (1), and ND (1). Isolation dates range from 10/10/19 to 12/15/2019, with onset dates between 10/7/2019 and 10/31/2019. 50% of cases have been hospitalized with 0 deaths. 40% are female. Cases range in age from 2 to 74 years old (median age: 25). Of the 11 cases with information available, 9 reported eating frozen pepperoni and/ or sausage pizzas. All 20 isolates have been sequenced in NCBI and are 0-4 SNPs apart, with an average of 1 SNP. There are no non-clinical isolates in the tree. Four cases report consuming a regionally distributed brand of frozen pizza, four cases report consuming a nationally distributed brand of frozen pizza, and the remaining cases ate various other brands of frozen pizza. MN tested a frozen pizza of the regional brand; results were negative for E. coli. A States call was held between CDC, FDA, FSIS, and MN on 12/5/2019 to share information on this the cluster and FSIS indicated they would follow up at the manufacturers (all dual jurisdiction establishments) to investigate ingredients used in the various pizzas reported by cases (all of which contained meat and were FSIS-regulated products). FSIS reported to CORE Signals on 12/19/2019 that the three manufacturers of interest may use crust from a common firm. MIN-DO is following up at the three pizza manufacturers to collect records to verify this commonality. MIN-DO is collecting records from three pizza manufacturers to determine more information about their crust supplier(s).

This incident transferred to CORE Response Team 4 on 1/6/2020, for further coordination. On 1/15/2020, CORE issued an assignment (# 145264) to HAF1W for record collection at Heggies Pizza LLC. (Milaca, MN). **On 1/16/20, CDC noted during the Tactics call that they believe the outbreak has ended.** On 1/22/2020, CORE issued an assignment to Office of Regulatory Affairs Human and Animal Foods Division 1 West (MIN-DO) for record collection at Bernatellos Pizza Inc. in Kaukauna, WI. **As of 1/27/20, HAF1W/MIN-DO completed the inspection at Heggies' Pizza LLC, in Milaca, MN (Assignment #145264).** CORE will continue to coordinate this investigation.

#### ***Listeria monocytogenes* (1901MLGX6-1)/Leafy Greens (suspect)/Dec 2019**

On December 11, 2019, CORE Signals was notified by CDC about a *Listeria monocytogenes* cluster with a signal for leafy greens. This cluster, 1901MLGX6-1, was previously evaluated by CDC and FDA CORE earlier in the year. At that time there was a signal for leafy greens; but the exposure information did not yield enough traceable information and was not detailed enough for any actions. The cluster was closed on April 12, 2019.

This re-opened cluster contains nine cases across eight states: IA, MD, NC, OH (2), OR, PA, TX, and WI. Isolation dates range from August 16, 2014 to November 20, 2019. Onset dates range from July 4, 2014 and November 1, 2019. There is one illness in 2014, three in 2018, and five in 2019. Four cases were added since the previous closure in April 2019. Ages range from 61 to 88 years (median 76). Seven (78%) of the cases are female. There are also two cases from Canada (British Columbia and Quebec provinces), that have isolates that

match this cluster by 1 allele. Onset dates for the Canadian illnesses were July 18, 2019 and September 4, 2019. Both were hospitalized and neither died.

All isolations are related within 0-10 alleles (median 0) and 0-15 SNPs (median 4). The NCBI SNP tree does not contain any food or environmental isolates or any other isolates other than the 9 clinical isolates. There is no genetic association between this cluster and other *L. monocytogenes* clusters. This incident transferred to CORE Response Team 4 on 1/14/2020, for further coordination. On 1/15/2020, CORE was informed by Office of Regulatory Affairs Human and Animal Food 5 East (CIN-DO) that OH Department of Agriculture collected a total of 31 retail samples of products produced by Dole: Dole American Blend Salad (4), Dole Garden Salad (5), Dole Cole slaw (5), Kroger Brand Garden Salad (5), Kroger Brand Cole slaw (5), Aldi/Little Salad Bar Garden salad (4) and Aldi-Southwest chopped salad kit (3). On 1/17/2020, ORA HAF 5 East reported that OH Department of Agriculture Lab found a presumptive positive for *Listeria* spp. in a sample of the Kroger Brand Coleslaw; all remaining samples were negative. On 1/24/2020, ORA HAF 5 East (CIN-DO) reported the final sample results for the Kroger Coleslaw product as positive for *Listeria welshimeri*. On 01/23/2020, CORE issued assignments to Office of Regulatory Affairs Human and Animal Food 3 East (ATL-DO) and Office of Regulatory Affairs Human and Animal Food 5 East (CIN-DO) for inspection, record collection and environmental/product sampling at two facilities: Dole Fresh Vegetables Inc. (Bessemer City, NC) and Dole Fresh Vegetables Inc. (Springfield, OH)

**On 1/27/20, Office of Regulatory Affairs Human and Animal Food 5 East (CIN-DO) and 3 East (ATL-DO) initiated their assignments at the Springfield, OH and Bessemer City, NC facilities respectively. These focused inspections included record collection, environmental swabbing, and end-product sampling. Both teams have collected environmental swabs and product samples. A firm call with Dole and CDC was held on 1/28/2020 to exchange exposure and epi information. The HAF 3E (ATL-DO) team plans to close-out next week with FDA 483 items which are currently under review. HAF 5E (CIN-DO) plans to close out on JAN 31 and does not plan to issue an FDA 483. Sub ingredient sourcing and processing information received from both teams are undergoing review. For the Springfield facility, analysis of Sample #1120077 consisting of 120 subsamples did not detect *Listeria* spp. and Sample #1136312 is still in progress. CORE will continue to coordinate.**

## **ON THE RADAR**

### **Novel Coronavirus (2019-nCoV)/Wuhan, China/2019**

On 1/31/2019, Chinese authorities informed the World Health Organization (WHO) of a cluster of cases of pneumonia of unknown cause detected in Wuhan City, Hubei Province of China. Chinese authorities subsequently identified the novel coronavirus (2019-nCoV) as the etiologic agent.

On 1/24/2020, CDC *confirmed* the second travel-related case of 2019-nCoV in Illinois is a patient returned to the U.S. from Wuhan on January 13, 2020. On 1/23/2020, the State Department ordered the departure from Wuhan, China of all U.S. Direct Hire (USDH) employees and Eligible Family Members (EFMs) and *issued* a level 4 travel advisory for Hubei province due to the 2019-nCoV first identified in Wuhan, China. On 1/23/2020, CDC *issued* a Level 3 warning, Avoid Nonessential Travel, for Wuhan, China.

FDA is working with the WHO, US government partners (e.g., NSC, HHS, ASPR, BARDA, CDC, NIH, DoD), and medical product developers as necessary to support international response efforts.

**On 1/27/2020, FDA Announced Key Actions to Advance Development of Novel Coronavirus Medical Countermeasures.** Also on 1/27/2020, FDA requested diagnostic test sponsors interested in potential Emergency Use Authorizations (EUA) for tests to detect 2019-nCoV to contact the CDRH at [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov). On 1/28/2020, the State Department repatriated 240 American Citizens from Wuhan, China. 40 HHS personnel are deployed in support of the repatriation mission.

**On 1/29/2020, the U.S. Department of State authorized the departure of family members and all non-emergency U.S. government employees at the U.S. Embassy in Beijing, China and the Consulates General in Chengdu, Guangzhou, Shanghai, and Shenyang.**

**As of 1/30/2020, 9,776 cases of 2019-nCoV have been reported with 213 deaths. On 1/30/2020, CDC confirmed that the 2019-nCoV has spread between two people in the United States, representing the first instance of person-to-person spread in the US. (2019 Novel Coronavirus (2019-nCoV) in the U.S.). On 1/30/2020, following the advice of the World Health Organization's Emergency Committee, WHO Director-General declared the outbreak of novel coronavirus (2019-nCoV) a Public Health Emergency of International Concern (PHEIC): declaration. Also on 1/30/2020, the White House announced the formation of the President's Coronavirus Task Force, which is charged with leading the United States Government response to the novel 2019 coronavirus and the WHO the 2019-nCoV outbreak a public health emergency of international concern.**

**On 1/31/2020, HHS Secretary Azar declared coronavirus a public health emergency in the US.**

#### **Interagency/NGO Coordination and Collaboration (OCET):**

- **USG Interagency:**
  - **FDA continues to participate in the daily 2019-nCoV briefing for the HHS Secretary, daily nCoV PCC held by NSC, HHS Supply Chain Task Force Meetings, and nCoV Stakeholder Industry calls hosted by BARDA.**
- **WHO:**
  - **on 1/28/2020, FDA participated in a WHO-USG Teleconference on Wuhan Coronavirus Cooperation.**

#### **Devices (CDRH):**

- **CDRH is maintaining continuous contact with USG agencies to discuss possible EUA requests. Additional IVD Developers have requested and received the EUA review template from CDRH.**
- **Interactive review of the CDC 2019-nCoV diagnostic test continues.**
- **DMD participated on a call with CDC and the American Clinical Laboratory Association (ACLA) and gave a brief overview of how to obtain the FDA EUA template for 2019-nCoV.**

#### **Drugs (CDER):**

- **CDER continues to work across the agency, with USG partners, and industry regarding nCoV response activities.**

#### **Biologics (CBER):**

- **Blood Supply Safety:**

- CBER continues to monitor the safety of the blood supply.
- CBER is developing guidelines for blood establishments to consider regarding blood donor education and self-deferral.
- **Tissues:** CBER continues to monitor potential effects of the nCoV outbreak on the tissue community.

#### **Communications (OMA):**

- **FDA published a new FDA webpage:** <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov/>
- **On 1/27/2020, FDA Announces Key Actions to Advance Development of Novel Coronavirus Medical Countermeasures**

#### **Fraudulent Product Claims:**

- **FDA received two reports about online sales of products promoted to prevent or treat 2019-nCoV 2019. ORA's Health Fraud Group is considering potential actions and discussing increased surveillance with CFSAN and CDER. The CDER Office of Compliance plans to execute a coronavirus surveillance plan that will cover both fraudulent and OTC products.**

#### **Medical Product Supply Chain:**

- **FDA has increased efforts to protect the medical product supply chain, including:**
  - **CDER's Drug Shortage Staff (DSS) contacted manufacturers of human medical drug products and requested status updates on the impact to availability of active pharmaceutical ingredient (API) and/or finished drug product due to the 2019-nCoV outbreak. To date, no manufacturers have reported an impact or drug shortages due to the outbreak in China.**
  - **CDER's Office of Pharmaceutical Quality (OPQ)/Office of Quality Surveillance (OQS) has identified manufacturing facilities in Wuhan, Hubei and the drug products that those sites make and created a CMS incident and added all the 24 API/FDF manufacturing facilities for further evaluation. OPQ/OQS will work with DSS if they find that any of these sites have products that could lead to shortage. They are also working with the Office of Regulatory Affairs (ORA) to identify scheduled surveillance inspections that have been put on hold and to discuss the potential use of other authorities to collect information from affected sites in lieu of inspection.**
  - **OPQ identified four facilities making drug products on the National Security Drug Products and Drug Shortage lists. OPQ is coordinating with drug shortage staff for these Hubei province findings and expanding the search to the rest of China.**
  - **To date, no manufacturers have reported an impact or drug shortages due to the 2019-nCoV outbreak in China.**
  - **OEM's GIS team developed and provided a map of the provinces of China for the Office of Regulatory Affairs and the Office of Global Operations.**

#### **Legislative Activities:**

- **Senate HELP staff requested a joint briefing on the 2019-nCoV response from CDC, NIH, ASPR, and FDA, likely early next week. HHS is coordinating HHS entities.**
- **On 1/30/2020, RADM Hinton, FDA Chief Scientist represented FDA at a member level briefing for the full House E&C committee.**

- **Bipartisan HELP Committee staff have requested a novel coronavirus briefing for next week with representatives from CDC, NIH, ASPR, and FDA. FDA Briefer TBD.**

**Budget:**

- **OMB, through HHS/ASFR, has requested a spending information by account on the coronavirus outbreak.**

**Workforce:**

- **Workforce Protection:**

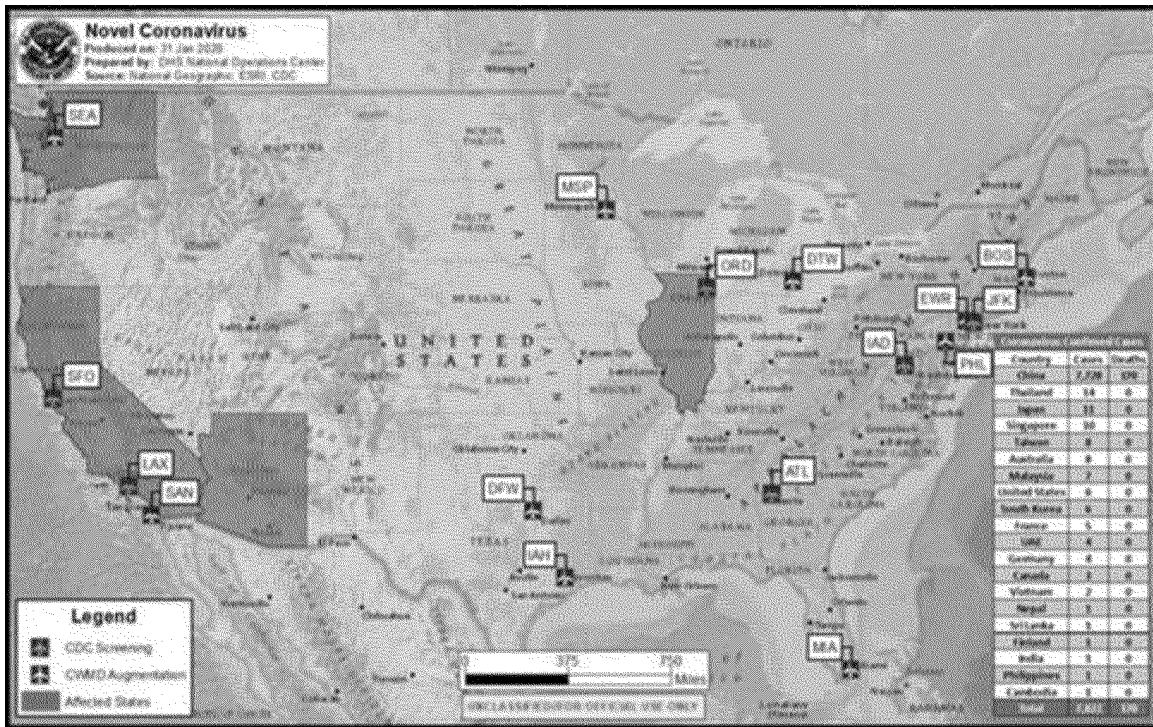
- **On 1/31/2020, the Office of Operations issued an *FDA Coronavirus Travel Advisory*, stating: “On January 30, 2020, the U.S. Department of State issued a Do Not Travel to China advisory. In addition, on January 29, 2020, they issued authorized departure for staff at the U.S. Embassy in Beijing and the Consulates General in Chengdu, Guangzhou, Shanghai, and Shenyang. Because of this, all official travel requires approval of the Undersecretary for Management at the State Department and all e-Country Clearance cables for travel in China have been canceled. In light of this advisory, the State Department’s authorized departure and available information on this outbreak, all FDA travel to China is hereby canceled until further notice. Any mission critical travel will be assessed on a case-by-case basis in coordination with the Department of Health and Human Services and the State Department.”**

- **Workforce Deployment: FDA USPHS officers deployed or rostered for deployment as of 1/31/2020:**

|              | Mission by Center        |          |                        |           |                        | Total     |
|--------------|--------------------------|----------|------------------------|-----------|------------------------|-----------|
|              | ACF Repatriation Mission |          | Corona Virus Screening |           | Puerto Rico Earthquake |           |
|              | Deployed                 | Rostered | Deployed               | Rostered  | Deployed               |           |
| CBER         |                          | 1        |                        | 2         |                        | 3         |
| CDER         | 3                        |          | 3                      | 18        |                        | 24        |
| CDRH         | 1                        |          |                        | 1         |                        | 2         |
| CFSAN        |                          |          | 1                      |           |                        | 1         |
| CTP          |                          |          | 1                      | 1         |                        | 2         |
| CVM          |                          |          |                        | 1         |                        | 1         |
| OC           | 1                        |          | 1                      |           |                        | 2         |
| ORA          | 2                        |          | 1                      | 3         | 1                      | 7         |
| <b>Total</b> | <b>7</b>                 | <b>1</b> | <b>7</b>               | <b>26</b> | <b>1</b>               | <b>42</b> |

**Map of US Confirmed cases and airport screening**





OEO will continue to monitor and provide updates.

### **Ebola Outbreak in Democratic Republic of Congo (DRC)**

The outbreak of Zaire ebolavirus (EVD) announced on 7/30/2018 by the Ministry of Health (MOH) of Democratic Republic of Congo (DRC) continues as the second largest Ebola outbreak ever recorded. On 10/18/2019, the WHO Director-General reconvened the Emergency Committee under the IHR (2005) for the Ebola Virus Disease to review progress in the implementation of the Temporary Recommendations issued by the Director-General on 7/17/2019. It was the view of the Committee this event still constitutes a PHEIC under the IHR. The Committee provided advice to the Director-General, who then issued revised *Temporary Recommendations* under the IHR.

The WHO Director-General is convening an IHR Emergency Committee for Ebola Virus Disease on 2/12/2020. The objectives of this meeting include the following:

- Review the current status of EVD in the Democratic Republic of the Congo.
- Provide views to the Director-General on whether the event continues to constitute a public health emergency of international concern (PHEIC).
- Provide views to the Director-General on the implementation of the Temporary Recommendations.

**One** health zone (HZs) reported **5** new confirmed cases in the past week in Nord Kivu Province of DRC. **Beni HZ** is the current hotspots of the outbreak. **Beni HZ** remains a concern after reporting all five new confirmed cases in the past week, all potentially linked to a single case but were not being followed. **Mabalako HZ** reported a confirmed case on 29 January after not reporting a case since 14 January (two weeks ago).

As the number of cases reported per week decreases compared to previous months, utmost attention is being given to investigating all new reported cases, identifying their contacts, and following up on these

**contacts. As observed in the past week, it is essential to detect new cases as early as possible in order to prevent further transmission in the community, as well as to conduct close and thorough investigations in those healthcare facilities that have admitted confirmed cases of EVD, in order to identify all contacts among healthcare workers and co-patients.**

**As of 1/28/2020, a total of 3421 cases (3302 lab confirmed, 119 probable), have been reported in 29 HZs (3 HZs in the past 21 days). 2,242 deaths have been reported (case fatality proportion 66%). During the past week, the number of active HZs (defined as having cases reported in the past 21 days) decreased from 5 HZs to 3 HZs. Beni HZ reported 5 confirmed cases this week.**

**Per data as of 1/28/2020, the total number of confirmed and probable healthcare worker (HCW) infections remains at 171 (+0).**

DRC Ebola epi numbers, as of close 30Jan20:

| Confirmed Cases | Probable Cases | Total Cases (C+P) | Deaths | Survivors |
|-----------------|----------------|-------------------|--------|-----------|
| 3,302           | 119            | 3,421             | 2,242  | 1,154     |

**Therapeutics:**

- **As of 1/29/2020, the PALM extension has enrolled 353 patients: 113 in Beni, 65 in Butembo, 40 in Katwa and 135 in Mangina.**

**Vaccine:**

- **As of 01/28/2020, 2791,050 individuals have been vaccinated.**
- **Ebola vaccination with the Ad26.ZEBOV / MVA-BN-Filo vaccine, produced by Janssen Pharmaceuticals for Johnson & Johnson, started on 11/14/2019 in two Karisimbi health areas in the city of Goma.**
- **Per CMRE as of 01/26/2020, 8,622 people have been vaccinated in the Janssen protocol.**

**Modeling: (No new updates)**

- **Estimating the number of Ebola cases and proportion of cases in effective isolation, The Democratic Republic of the Congo, 2018-2019 (v3.26, 15 January 2020):**
  - **Percent effectively isolated: Based on 3,406 total cases reported as of 14 January 2020, the estimate of the proportion of cases effectively isolated is 55%.**
  - **Projected number of cases: Assuming that the proportion of Ebola cases effectively isolated remains unchanged at 55%, the outbreak is projected to continue beyond December 2020 with an estimated cumulative total of 3,553 cases.**
  - **Outbreak continues: Projections indicate that if the proportion of cases effectively isolated remains at 55%, the number of new cases each week will decline slowly through the end of 2020.**
  - **By the end of 2020, there will be approximately 1 new case each week.**

- Sensitivity analysis: The projected number of future cases is very sensitive to the proportion of cases that are effectively isolated.
  - If the proportion of cases that are being effectively isolated is decreased from 55% to 45%, the model indicates that the number of cases will continue to increase beyond the analytic horizon. In this scenario, the outbreak continues beyond December 2020.
  - If the proportion of cases that are effectively isolated is raised from 55% to 65% from 25 January onward, the outbreak will end by 26 June 2020 with a total of 3,473 total cases.
- To bring a rapid end to the outbreak, the proportion of cases in effective isolation, ideally within 3 days of symptom onset, will need to reach and be sustained at approximately 70%.

### **FDA Response Activities:**

FDA continues to support the response to the Ebola outbreak in the DRC. Key activities include working with interagency partners, medical product developers, the World Health Organization, and international regulatory counterparts to help advance the development and availability of vaccines, treatments, and diagnostic tests for Ebola.

- December 19, 2019: *First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response* - FDA announced today the approval of Ervebo, the first FDA-approved vaccine for the prevention of Ebola virus disease (EVD), caused by *Zaire ebolavirus* in individuals 18 years of age and older. Cases of EVD are very rare in the U.S., and those that have occurred have been the result of infections acquired by individuals in other countries who then traveled to the U.S., or health care workers who became ill after treating patients with EVD. Because of the public health importance of a vaccine to prevent EVD, the FDA worked closely with the company and completed its evaluation of the safety and effectiveness of Ervebo in less than six months.

For additional information related to FDA's Ebola Response and Activities, please click on the following link: [\*FDA's Ebola Response\*](#). OEO will continue to monitor situation reports from WHO, HHS, and CDC and provide updates as necessary.

### **Industrial Explosion/Houston, Texas/Jan 2020**

On 1/24/20, there was a massive explosion in a northwest Houston neighborhood around 4:25 am (local time). The origin of the explosion was at a machining and manufacturing company. Nearby structures appeared to be destroyed in the blast.

Initial indications are that the explosion possibly involved propylene, oxygen, nitrogen, and compressed air, other chemicals on site may have been affected. The Houston Fire Department Hazardous Materials Team stopped the flow of propylene, oxygen and nitrogen to the site. There were no fatalities and two injuries. There are no concerns at this time with air quality and no evacuations have been ordered at this time. The Cybersecurity and Infrastructure Security Agency reports the manufacturing plant is not a Chemical Facility Anti-Terrorism Standards facility. OEM's Geographic Information Specialists generated a spatial assessment of the explosion and found five FDA regulated firms within a mile of this explosion. This information was passed on to the District Office for their follow up. The Dallas District Office reported that all employees are safe and accounted for. **No reports of adverse effects on FDA-regulated industry were reported.** OEO will **no longer** continue to monitor.

**Magnitude 6.7 Earthquake/Eastern Turkey/Jan 2020**

On 1/24/20, OEO was notified of a magnitude 6.7 earthquake struck central-eastern Turkey at a depth of approximately 6.2 miles, according to the U.S. Geological Survey (USGS). The epicenter of the earthquake was located approximately 2.5 miles east-northeast of Doğanyol town in Malatya Province. The United State Geological Survey (USGS) issued a yellow alert for estimated economic losses and a green alert for earthquake-related fatalities, indicating that some damage is possible, while impacts should be relatively localized, and there is a low likelihood of casualties. FDA's Division of Travel Operations confirmed no travelers are currently in Turkey. OEO will no longer report on this incident unless warranted.

**Vessel Collision/New Orleans, LA/Jan 2020**

The United States Coast Guard (USCG) reported the Inspected Towing Vessel (ITV) RC CREPPEL, which was headed down bound on the Lower Mississippi River (LMR), sank after being struck by an upbound barge being pushed by the ITV COOPERATIVE SPIRIT near New Orleans, LA. Portions of the LMR between mile markers 121 and 123 are closed.

At approximately 0637 ET 1/26/20, the upbound ITV COOPERATIVE SPIRIT suffered a major barge breakaway of approximately 40 barges as it entered a barge fleeting area near MM 123 on the LMR. The ITV RC CREPPEL, traveling down bound and pushing two "red flag" barges of sulfuric acid (one barge loaded and one empty) was struck by one of the breakaway barges and sank. One of the RC CREPPEL'S barges was venting an unknown quantity of sulfuric acid into the atmosphere. The air release was later secured by the barge's vapor control system. St. Charles Parish officials said there were no immediate health concerns. The safety zone and the TFR will remain until air quality is cleared safe. OEO notified the local district office who reported no impacts. OEO will no longer report on this incident unless warranted.

**Explosive Device At Federal Courthouse Rendered Safe; Suspicious Device /Anchorage, AK/ Jan 2020**

On 1/27/2020, an improvised explosive device that was found at the Anchorage Federal Courthouse Monday afternoon local time was rendered safe, according to a spokesman for the local FBI office. FBI Special Agent Bomb Technicians and an Anchorage Police Department Bomb Squad responded and rendered the item safe, according to the spokesman. They added that no one was injured, and that the investigation continues. FBI agents do not believe there is any additional risk to our community. FDA's local District Office performed personal accountability of its Anchorage, AK staff; there was no effect on FDA personnel. OEO will no longer continue to monitor.

**M 7.7 Earthquake/ Cuba region/Jan 2020**

On 1/28/2020, a M 7.7 earthquake struck the Cuba region of the Caribbean Sea; a tsunami warning was issued for the region, potentially affecting Jamaica, Cuba and the Cayman Islands. OEO provided this information to FDA travel offices, which confirmed that there are no FDA travelers in those three countries. OEO will continue to monitor, but no longer report unless warranted.

<sup>1</sup> Bold text indicates new information.

**ORA Weekend Duty Manager  
CORE Duty Officer**

**Vinetta Howard-King  
Elisa Elliott**

**MEETINGS AND CONFERENCES:**

**January 27-31 2020** – 2020 Novel Coronavirus Conference calls – (Participants from OEO) Discuss planning and response efforts among HHS agencies and external partners

**January 28, 2020-** RNC, DNC, Inauguration FDPA Steering Committee Weekly Meeting (OEM: J Simms, T Mignone) Discuss planning efforts for 2020 NSSEs,

**January 29, 2020** - FEMA Master Event Scenario List (MSEL) Scripting Meeting - OEM/EPEES (Participant: CAPT Mignone) - Participated in Day 2 of the meeting to synchronize FDA play with HHS and other exercise participants.

**January 30, 2020** - Cyber Incident Response Workshop Initial Planning Meeting (IPM) – OEM/EPEES (Participant: CAPT Mignone) - Planning ramp up event for National Level Exercise (NLE) 2020.

**January 30, 2020** - Biosafety Lab Exercise Planning Meeting – OEM/EPEES (Participant: D. Estes) - Finalize Situation Manual for BSL FE.

**January 31, 2020** - African Swine Fever Workgroup Meeting – OEM/EPEES (Participant: D. Estes) - Develop an FDA African Swine Fever Response Plan

v/r

CAPT Dominic Frasca

Staff Manager, FDA Office of Emergency Operations

3017968246

BB [redacted] (b)(6)

Group email:emergency.operations@fda.hhs.gov

---

**From:** Russ, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2900752ACF81445785FB0F5B23C728C8-WRUSS]  
**Sent:** 2/3/2020 8:07:53 AM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** FW: MCMimpact: Medical countermeasure updates from across FDA - January 2020

Share with Dr. Hahn.

---

**From:** U.S. Food and Drug Administration <fda@info.fda.gov>  
**Sent:** Monday, February 03, 2020 7:35 AM  
**To:** FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Subject:** MCMimpact: Medical countermeasure updates from across FDA - January 2020

-----  
If your email program has trouble displaying this email, view it as a [web page](#).

-----

# January 2020

For FDA internal distribution only

This MCMimpact brief highlights key FDA accomplishments and activities to advance the development and availability of medical countermeasures (MCMs) to respond to chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats as well as MCMs to support the unique needs of US military personnel.

## CBRN Threats and Pandemic Influenza

- **Product approval** (January 31) – FDA approved AUDENZ, (Influenza A (H5N1) Monovalent Vaccine, Adjuvanted) for active immunization for the prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine. AUDENZ is approved for use in persons 6 months of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine. This vaccine will be produced and distributed under contract to the U.S. Government as part of national pandemic preparedness initiatives.
- **Expiration date extensions** (January 10) – FDA alerted health care providers and emergency responders of two additional lots of DuoDote (auto-injectors for use during nerve agent emergencies) that are no longer useable and should be

disposed of properly.

## Emerging Infectious Diseases

- **Response to novel coronavirus (2019-nCoV)** – FDA is monitoring this dynamic situation and collaborating closely with interagency partners as well as with international partners and medical product developers and to help advance response efforts. MCM-related January activity highlights include:
  - **Diagnostics:** CDRH has been working closely with CDC to facilitate CDC's development of a diagnostic test. OCET has been working with HHS to ensure the necessary determination and declaration are ready for issuance of an Emergency Use Authorization (EUA) sponsored by CDC. CDRH developed a draft template to support EUA submissions and is making it available to test developers (19 firms as of 10:00 a.m., January 31).
  - **Other potential MCMs:** FDA is working with interagency partners to identify potential MCMs that may be relevant and providing regulatory advice, guidance, and technical assistance to help expedite the regulatory process and advance the development and availability of MCMs as rapidly as possible.
  - **Web page:** FDA has established an agency-wide landing page for this response at [www.fda.gov/novelcoronavirus](http://www.fda.gov/novelcoronavirus).
  - **FDA SITREPS:** FDA is producing daily SITREPS to track activities.
  - **Ebola outbreak in Democratic Republic of Congo (DRC) response** (ongoing) – FDA continued to support response to the Ebola outbreak in DRC. Key activities included working with interagency partners, medical product developers, and WHO, to help move investigational medical products for Ebola forward in development as quickly as possible; facilitating access to available medical products through appropriate regulatory mechanisms when necessary; and protecting consumers from fraudulent products and false product claims related to Ebola. (*Also see: Ebola Preparedness and Response Updates from FDA*) Key accomplishments in January include:
    - FDA (OCET) is assisting CDC with data management training for surveillance and case tracking.

## Enhanced Engagement with DoD

- **CDRH/JPC-1 Autonomous Systems Meeting** (January 24) – CDRH met with JPC-1 on the DoD's desire to develop **(b)(4) (b)(5)**. The meeting also included representatives from Navy, Air Force, and Army. Each of the military branches discussed development efforts in these areas. CDRH will continue to engage with DoD on determining the regulatory path for **(b)(4) (b)(5)**.

## MCM-Related Publications by FDA

- Rios, M (CBER). Glucanase report on chikungunya, dengue and Mayaro virus, part 2: epidemiological distribution of dengue virus. *Antiviral Res* 2019 Dec;172:104611.
- Verdun N (CBER). Pathogen reduction of blood components during outbreaks of infectious diseases in the European Union: an expert opinion from the European Centre for Disease Prevention and Control consultation meeting. *Blood Transfus* 2019 Nov;17(6):433-48.
- Weir JP (CBER). Meeting report and review: immunological assays and correlates of protection for next-generation influenza vaccines. *Influenza Other Respir Viruses* 2019 Dec 13 [Epub ahead of print].
- Vardon P, Sassi A (OC). Fukushima: U.S. response and the short-term impact on U.S.-Japan trade in fish and seafood. *J*

Benefit Cost Anal 2019 Fall;10(3):351-78.

- Thirunavvukarasu N, Singh A, Chapman C, Avila JR, Pillai CA, Manickam G (CFSAN), Pillai SP (OC). Comprehensive laboratory evaluation of a lateral flow assay for the detection of *Yersinia pestis*. Health Secur 2019 Nov-Dec;17(6):439-53.
- MCMi Regulatory Science Program – Extramural research project publications:
  - Davis C. et. Al (2019) Post-exposure prophylaxis with rVSV-ZEBV following exposure to a patient with Ebola virus disease relapse in the UK: an operational, safety and immunogenicity report. Clin Infect Dis. 2019 Nov 30.
  - Logue J. et al. (2019) Innovative Technologies for Advancement of WHO Risk Group 4 Pathogens Research. In: Shapshak P. et al. (eds) Global Virology III: Virology in the 21st Century. Springer, Cham.
  - Wyss institute's organ chip project partially funded by FDA was described in Nature Biomedical Engineering, as featured in a Wyss news release.

## Upcoming Events

- **February 3, 2020: Public** – Advancing EUA IVD Products Toward Full Marketing Status workshop (Silver Spring, MD) – Hosted by FDA and the Medical Device Innovation Consortium (MDIC), this workshop will explore key considerations for using real world data (RWD) to generate real world evidence (RWE) to help support in vitro diagnostic (IVD) products available under FDA's EUA to advance to full marketing status. FDA Chief Scientist RADM Denise Hinton will present.
- **February 11-12, 2020: By invitation** – WHO meeting - Global Forum on Research and Innovation: Towards a Roadmap for the 2019 novel Coronavirus, Geneva, Switzerland. FDA will be sending representatives.
- **February 25-26, 2020: Public** – Developing Medical Countermeasures to Treat the Acute and Chronic Effects of Ocular Chemical Toxicity (Rockville, MD) – A trans-agency meeting organized by DoD and NIH (NIAID and NEI).
- **March 3-5, 2020: Public** – Mitigating the Impact of Blast-related Burn Injuries: From Prolonged Field Care to Rehabilitation and Resilience (Arlington, VA), hosted by the DoD Blast Injury Research Coordinating Office, U.S. Army Medical Research and Development Command, on behalf of the DoD Executive Agent for Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries.
- **March 31 - April 3, 2020: Public** – Preparedness Summit (Dallas, TX) – Hosted by the National Association of County & City Health Officials (NACCHO). FDA staff will present with other federal partners on public health preparedness and response issues including MCM emergency use and stockpiling (Brooke Courtney, OCET), diagnostics (Kim Sapsford, CDRH), and preparedness communication (April Finnen, OCET and Jovonni Spinner, OMMHE).
- **April 20-24, 2020: Public** – Training Course: Achieving Data Quality and Integrity in Maximum Containment Laboratories (Bethesda, MD) – A collaboration between the University of Texas Medical Branch (UTMB) and OCET, this popular course offers a unique opportunity for the regulatory and scientific communities to discuss complex issues in an interactive environment and identify and share best practices for ensuring data quality and integrity in BSL-4 facilities. There is no cost to attendees, but seating is limited. To express interest in attending, follow the instructions on this page to submit your information by **February 28, 2020**. (Registration for the companion clinical course in July will open April 6, 2020.)

*Note: We continue to update MCM-related issues pages with information from across FDA. To ensure that your center/office's MCM and response-related updates are included, please send links to or CC april.finnen@fda.hhs.gov on communications planning.*



U.S. Food and Drug Administration  
10903 New Hampshire Avenue, Silver Spring, MD 20993  
1-888-INFO-FDA (1-888-463-6332)

[Privacy Policy](#) | [www.fda.gov](http://www.fda.gov)

[Manage Preferences](#) or [Unsubscribe from this List](#) | [Unsubscribe from all Email Lists](#)



---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/3/2020 2:42:23 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**Subject:** For review asap: employee email on outbreak response  
**Attachments:** Dear Colleagues.docx

Please review the attached as soon as possible. The plan is to send this today. Will also print you a hard copy. Thank you.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/3/2020 3:37:10 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Tentative: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/3/2020 3:15:00 PM  
**End:** 2/3/2020 3:45:00 PM  
**Recurrence:** (none)

---

**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 2/3/2020 5:01:40 PM  
**To:** Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: TWEETS for REVIEW: nCOV - Workshop/Blood Supply/USPHS Meeting

Thanks, Brad

(b)(5)

---

**From:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Sent:** Monday, February 3, 2020 4:56 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>  
**Subject:** TWEETS for REVIEW: nCOV - Workshop/Blood Supply/USPHS Meeting

Good evening... three tweet threads for your review. For your awareness, these are being reviewed concurrently at HHS. (b)(5)

Thanks! –Brad

===

#### WORKSHOP

1. Today, FDA cohosted a public workshop with @MDIConline on Advancing Emergency Use Diagnostic Products Toward Full Marketing Status. Planned well before the #coronavirus outbreak, it's especially timely now.

<http://bit.ly/36WxpC2> [PHOTO]

2. The workshop explored key considerations for using real world evidence to transition EUA authorized devices to full marketing status. We're continuing our collaborative work across the public and private sector to prepare, mitigate and respond to outbreaks.

#### BLOOD SUPPLY

3. The safety of the nation's blood supply is a top FDA priority. We've received questions about the potential impact of the novel coronavirus (2019-nCoV) on blood safety. Respiratory viruses are generally not known to be transmitted via blood transfusion.

4. Routine donor screening that already takes place should prevent individuals with respiratory infections including 2019-nCoV from donating blood. Donors must be in good health and have a normal temperature when they donate.

5. As a precaution, FDA has provided information to blood establishments may wish to consider for providing donor education, encouraging self-deferral and managing post-donation information in response to the 2019-nCoV outbreak. [\[LINK\]](#)

(b)(5)

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-1002

(b)(6)

[brad.kimberly@fda.hhs.gov](mailto:brad.kimberly@fda.hhs.gov)



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/3/2020 5:47:37 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FDA nCoV Update February 3, 2020  
**Attachments:** 08\_2019-nCoV Outbreak\_FDA SITREP\_03 February 2020.docx

Today's CoV sit rep is attached. Thanks.

Internal confidential pre decisional deliberative

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/3/2020 7:50:35 PM  
**To:** Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]  
**CC:** Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]  
**Subject:** Re: TWEETS for REVIEW: nCOV - Workshop/Blood Supply/USPHS Meeting

Approved. Agree with Anand's comments  
Thx  
S

---

**From:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Date:** February 3, 2020 at 4:55:54 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>  
**Subject:** TWEETS for REVIEW: nCOV - Workshop/Blood Supply/USPHS Meeting

Good evening... three tweet threads for your review. For your awareness, these are being reviewed concurrently at HHS. [REDACTED]

Thanks! –Brad

===

#### WORKSHOP

1. Today, FDA cohosted a public workshop with @MDIConline on Advancing Emergency Use Diagnostic Products Toward Full Marketing Status. Planned well before the #coronavirus outbreak, it's especially timely now.  
<http://bit.ly/36WxpC2> [PHOTO]

2. The workshop explored key considerations for using real world evidence to transition EUA authorized devices to full marketing status. We're continuing our collaborative work across the public and private sector to prepare, mitigate and respond to outbreaks.

#### BLOOD SUPPLY

3. The safety of the nation's blood supply is a top FDA priority. We've received questions about the potential impact of the novel coronavirus (2019-nCoV) on blood safety. Respiratory viruses are generally not known to be transmitted via blood transfusion.

4. Routine donor screening that already takes place should prevent individuals with respiratory infections including 2019-nCoV from donating blood. Donors must be in good health and have a normal temperature when they donate.

5. As a precaution, FDA has provided information to blood establishments may wish to consider for providing donor education, encouraging self-deferral and managing post-donation information in response to the 2019-nCoV outbreak. [\[LINK\]](#)

(b)(5)

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration

Tel: 240-402-1002 | (b)(6)

[brad.kimberly@fda.hhs.gov](mailto:brad.kimberly@fda.hhs.gov)





---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/3/2020 7:51:36 PM  
**To:** Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]  
**Subject:** Read: ACTION REQUIRED- FDA Agency Executive Group/Incident Management Group Activation Notice- Outbreak of 2019 Novel Coronavirus (2019-nCoV)

**Importance:** High

Your message

**To:** FDA Commissioner; Hahn, Stephen; Abernethy, Amy; Lenihan, Keagan; Sigg, Jim; Hebert, Angelique A.; Caliguiri, Laura; Amin, Stacy; McWilliams, Carly; Gross, Karas; Abram, Anna; McMeekin, Judith; Solomon, Steven M; Hinton, Denise; Mair, Michael; Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cave, Carol; Rogers, Michael; Morrison, Ellen F; Demers, Donald E; Branch, Tiffany; Abdo, Mark

**CC:** Mayne, Susan; Carter, Lionel; Kux, Leslie; Clarke, Mary Beth; Roth, Lauren; McBride, Maren; Dickinson, Elizabeth (FDA); Howard, Paul I.(OC; Raza, Mark; Schwartz, Suzanne; Leissa, Brad G; Roberts, Rosemary; CVM ECRS; Glover, Mark; Rotstein, David; Hodges, April; Woody, Jon; Jackson, LeeAnne; Marders, Julia A; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Peters, Kristina E; Scire, Nicholas J; Livsey, Kimberly; Yee, James C; McSeveney, Megan; Zeller, Mitchell; OO-OSEM-OEM-staff; Amann, Matthew J; Gutierrez, Sacha

**Subject:** ACTION REQUIRED- FDA Agency Executive Group/Incident Management Group Activation Notice- Outbreak of 2019 Novel Coronavirus (2019-nCoV)

**Sent:** 2/3/2020 4:32:06 PM

was read on 2/3/2020 7:51:36 PM

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/4/2020 10:41:20 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; anderson, erika; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; anderson, erika; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A.  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Rebello, Heidi  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shuren, Jeff  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Woodcock, Janet  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Solomon, Steven M  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; McMeekin, Judith  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Carter, Lionel  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Hahn, Stephen  
 [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP  
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Sigg, Jim  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A.  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Rebello, Heidi  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shuren, Jeff  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Woodcock, Janet  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Solomon, Steven M  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; McMeekin, Judith  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Carter, Lionel  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]

**Subject:** Commissioner Briefing: IMG

**Location:** OO Conference Room (WO2/3305) or 1-877-465-7975,,

(b)(6)

---

**Start:** 2/4/2020 5:00:00 PM

**End:** 2/4/2020 5:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Amin, Stacy; Hinton, Denise; Mair, Michael; Shah, Anand; Rom, Colin; Caliguiri, Laura

#### Agenda

2019-nCoV IMG 101 Overview – 10 minutes

Interagency Engagement – MCM & Supply Chain – 5 min

Information Flow – AEG - General Reporting/Updates – 5 minutes

2019-nCoV Agency Executive Group – 5 min

Questions/Discussion - 5 minutes

Deeper dive on shortages to follow in subsequent brief.

We will also adjust based on Dr. Hahn's feedback on the first brief.

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/4/2020 11:36:40 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Fwd: FOR SH IMMEDIATE REVIEW: Coronavirus EUA PR quote  
**Attachments:** For SH Review - cov diagnostic eua\_PR-2.4.20.docx  
**Importance:** High

Dr. Hahn—

Please review ASAP when you have a second so we can move forward with press release

---

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/4/2020 1:36:15 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: FOR SH IMMEDIATE REVIEW: Coronavirus EUA PR quote

Perfect

Thanks!

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Tuesday, February 4, 2020 1:36 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: FOR SH IMMEDIATE REVIEW: Coronavirus EUA PR quote

(b)(5)

Sent from my iPhone

On Feb 4, 2020, at 12:16 PM, Rom, Colin <Colin.Rom@fda.hhs.gov> wrote:

(b)(5)

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Tuesday, February 4, 2020 12:15 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** RE: FOR SH IMMEDIATE REVIEW: Coronavirus EUA PR quote

(b)(5)

(b)(5)

Let me know if I need to talk to him.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Tuesday, February 4, 2020 12:13 PM  
**To:** Janik, Heather <Heather.Janik@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** RE: FOR SH IMMEDIATE REVIEW: Coronavirus EUA PR quote

(b)(5)

**(b)(5)**

Thanks!

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/4/2020 2:37:18 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Watters, Sam W (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4731d001d89d45319792bd2fe2490514-HHS-Sam.Wat]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FDA Heads Up for HHS NN - 2/5/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/5/20:

- **FDA to continue to highlight actions in response to 2019-nCoV**

Tomorrow, FDA is expected to continue to communicate on its work in response to the Novel Coronavirus Outbreak (2019-nCoV) as necessary.

- **FDA to hold meeting on oncology drug development**

Tomorrow, FDA's Oncology Center of Excellence (OCE) will be holding a public meeting/workshop to update the public on some of the major innovations and programs at OCE as well as mark the initiation of the third year of OCE.



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/4/2020 4:16:29 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mignone, Alfred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]  
**Subject:** Materials: Commissioner Briefing: IMG  
**Attachments:** FDA 2019-nCoV Response.pptx

Please see attached materials for today's 5 PM: *Commissioner Briefing: IMG*.

Thank you,  
Frank

-----Original Appointment-----

**From:** Sheehy, Janice **On Behalf Of** Hahn, Stephen

**Sent:** Tuesday, February 4, 2020 10:41 AM

**To:** Hahn, Stephen; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov);

Amin, Stacy; Hinton, Denise; Mair, Michael; Mignone, Alfred; Shah, Anand; Rom, Colin; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Anderson, Erika; Sigg, Jim; Hebert, Angelique A.; Rebello, Heidi; Shuren, Jeff; Woodcock, Janet; Marks, Peter; Solomon, Steven M; McMeekin, Judith; Carter, Lionel

**Subject:** Commissioner Briefing: IMG

**When:** Tuesday, February 4, 2020 5:00 PM-5:30 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** COO Conference Room (WO2/3305) or 1-877-465-7975, (b)(6)

#### Agenda

2019-nCoV IMG 101 Overview – 10 minutes

Interagency Engagement – MCM & Supply Chain – 5 min

Information Flow – AEG - General Reporting/Updates – 5 minutes

2019-nCoV Agency Executive Group – 5 min

Questions/Discussion - 5 minutes

Deeper dive on shortages to follow in subsequent brief.

We will also adjust based on Dr. Hahn's feedback on the first brief.

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/4/2020 5:06:51 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FDA SITREP 04 FEB  
**Attachments:** 09\_2019-nCoV Outbreak\_FDA SITREP\_04 February 2020.docx

Today's COV sit rep is attached.

Internal confidential

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdoo, Mark [Mark.Abdoo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]  
**Subject:** nCoV Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: (b)(6)  
**Start:** 2/5/2020 5:15:00 PM  
**End:** 2/5/2020 5:45:00 PM  
**Show Time As:** Tentative  
**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, Thursday, and Friday from 5:15 PM to 5:45 PM  
**Required Attendees:** Hahn, Stephen; Keagan Lenihan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M

AEG meetings have been established to address policy and resource issues related to the nCoV public health emergency. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

---

CC: [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]  
Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1bf7cb4c1d287f83e-ChoD]; Caccamo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** COVID-19 Agency Executive Group Meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: (b)(6) or Conference Room (WO1/2102)  
**Start:** 3/2/2020 8:30:00 AM  
**End:** 3/2/2020 8:45:00 AM  
**Show Time As:** Tentative  
  
**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, Thursday, and Friday from 8:30 AM to 8:45 AM

---

**Required** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William;  
**Attendees:** Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael;  
McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair,  
Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie;  
Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia

The meeting time has changed to provide updates in advance of TF calls. Thank you in advance for your cooperation in accommodating the schedule change. Note the location change to Bldg. 1, RM 2102 as well.

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

## **AEG DAILY CHECKLIST**

### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

### **Inspection Delays (ORA)**

### **Travel Advisories (AIC)**

### **UFA Deadlines At-Risk (ORA/Centers)**

### **Personnel Considerations/Workforce Management (OO)**

### **Other pressing issues**

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdo, Mark [Mark.Abdo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Throckmorton, Douglas C [Douglas.Throckmorton@fda.hhs.gov]; Solberg, Tim [Tim.Solberg@fda.hhs.gov]; Keller, Melanie [Melanie.Keller@fda.hhs.gov]; Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Tyler, James [James.Tyler@fda.hhs.gov]; Beach, Carter [Carter.Beach@fda.hhs.gov]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]  
**CC:** Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Malais, Tanya [Tanya.Malais@fda.hhs.gov]; Janik, Heather [Heather.Janik@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Ricci, Linda J [Linda.Ricci@fda.hhs.gov]; O'Callaghan, Kathryn [Kathryn.O'Callaghan@fda.hhs.gov]; Lynch, Sarah [Sarah.Lynch@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Bess, Demetrice [Demetrice.Bess@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Caccamo, Stephanie [Stephanie.Caccamo@fda.hhs.gov]; Ross, Bruce [Bruce.Ross@fda.hhs.gov]; Torres-Rivera, Sahra [Sahra.Torres-Rivera@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]  
**Subject:** COVID-19 Agency Executive Group Meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: (b)(6) or COO Conference Room (WO2/3305)  
**Start:** 3/2/2020 9:15:00 AM  
**End:** 3/2/2020 9:30:00 AM  
**Show Time As:** Busy  
**Recurrence:** Weekly  
Occurs every weekday from 9:15 AM to 9:30 AM effective 3/2/2020 until 6/5/2020.  
**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.



## **AEG DAILY CHECKLIST**

### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

### **Inspection Delays (ORA)**

### **Travel Advisories (AIC)**

### **UFA Deadlines At-Risk (ORA/Centers)**

### **Personnel Considerations/Workforce Management (OO)**

### **Other pressing issues**

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Bea]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]

**CC:** Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** COVID-19 Agency Executive Group Meeting

**Attachments:** Untitled Attachment; Untitled Attachment; nCoV Agency Executive Group meeting - Note time change; nCoV Agency Executive Group meeting; COVID-19 Agency Executive Group meeting

**Location:** 1-877-465-7975, code: (b)(6) or COO Conference Room (WO2/3305)

**Start:** 3/2/2020 9:15:00 AM

**End:** 3/2/2020 9:30:00 AM

**Show Time As:** Tentative

**Recurrence:** Weekly

every Monday, Tuesday, Wednesday, Thursday, and Friday from 9:15 AM to 9:30 AM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle,

William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael;

---

McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; James Tyler; Beach, Carter; Cavazzoni, Patrizia

AEG meetings have been established to address policy and resource issues related to the COVID-19 outbreak. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

AEG representatives from Centers/Offices will provide high-level updates on key issues and activities in their respective areas.

## **AEG DAILY CHECKLIST**

### **Medical Product Updates**

- Diagnostics
- Therapeutics
- Vaccines
- Personal Protective Equipment (PPE)
- Clinical Trial Updates

### **Supply Chain/Shortage Updates**

- CDER
- CDRH
- CBER
- CFSAN
- CVM

### **Inspection Delays (ORA)**

### **Travel Advisories (AIC)**

### **UFA Deadlines At-Risk (ORA/Centers)**

### **Personnel Considerations/Workforce Management (OO)**

### **Other pressing issues**

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fecae0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas

---

**CC:** C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO] Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]

**Subject:** nCoV Agency Executive Group meeting

**Attachments:** Untitled Attachment; Untitled Attachment; Canceled: Canceled: nCoV Agency Executive Group meeting; nCoV Agency Executive Group meeting - Note time change

**Location:** 1-877-465-7975, code: (b)(6) pr COO Conference Room (WO2/3305)

**Start:** 2/5/2020 5:15:00 PM

**End:** 2/5/2020 5:45:00 PM

**Show Time As:** Busy

**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, and Thursday from 5:15 PM to 5:45 PM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C

AEG meetings have been established to address policy and resource issues related to the nCoV public health emergency. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Hebert, Angelique A. [Angelique.Hebert@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Solomon, Steven M [Steven.Solomon@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Abdo, Mark [Mark.Abdo@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Branch, Tiffany [Tiffany.Branch@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Caliguiri, Laura [Laura.Caliguiri@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Musser, Steven M [Steven.Musser@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Throckmorton, Douglas C [Douglas.Throckmorton@fda.hhs.gov]  
**CC:** Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Tyler, James [James.Tyler@fda.hhs.gov]  
**Subject:** nCoV Agency Executive Group meeting  
**Attachments:** Untitled Attachment; Untitled Attachment; Canceled: Canceled: nCoV Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: (b)(6) or COO Conference Room (WO2/3305)  
**Start:** 2/5/2020 5:15:00 PM  
**End:** 2/5/2020 5:45:00 PM  
**Show Time As:** Busy  
**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, and Thursday from 5:15 PM to 5:45 PM  
**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C

AEG meetings have been established to address policy and resource issues related to the nCoV public health emergency. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/4/2020 9:31:56 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0a0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]

**Subject:** nCoV Agency Executive Group meeting

**Location:** 1-877-465-7975, code: (b)(6)

**Start:** 2/5/2020 5:15:00 PM

**End:** 2/5/2020 5:45:00 PM



---

**Show Time As:** Free

**Recurrence:** Weekly  
every Monday, Tuesday, Wednesday, Thursday, and Friday from 5:15 PM to 5:45 PM

**Required Attendees:** Hahn, Stephen; Keagan Lenihan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M

AEG meetings have been established to address policy and resource issues related to the nCoV public health emergency. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/5/2020 9:45:47 AM  
**To:** Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**CC:** Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]  
**Subject:** Re: TWEET for REVIEW: Senior Leader Meeting

Approved  
Thanks  
Steve

---

**From:** "Kimberly, Brad" <Brad.Kimberly@fda.hhs.gov>  
**Date:** Tuesday, February 4, 2020 at 6:31 PM  
**To:** Anand Shah <Anand.Shah@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** "Stark, Angela" <Angela.Stark@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Laura Caliguiri <Laura.Caliguiri@fda.hhs.gov>, "Janik, Heather" <Heather.Janik@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Heidi Rebello <Heidi.Rebello@fda.hhs.gov>, "Thorpe, Valarie" <Valarie.Thorpe@fda.hhs.gov>  
**Subject:** RE: TWEET for REVIEW: Senior Leader Meeting

Copy that. Standing by for the greenlight.

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-1002 | Cell: (b)(6)  
brad.kimberly@fda.hhs.gov



---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>

**Sent:** Tuesday, February 4, 2020 6:31 PM

**To:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>

**Subject:** RE: TWEET for REVIEW: Senior Leader Meeting

Brad – our emails must’ve just crossed... [REDACTED] (b)(5) ]Thx

---

**From:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

**Sent:** Tuesday, February 4, 2020 6:28 PM

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>

**Subject:** TWEET for REVIEW: Senior Leader Meeting

Good evening... here’s one more tweet for your review. Thanks! --Brad

===

### Meeting

I couldn’t be more impressed with the highly talented team here at FDA as we address the #coronavirus. [REDACTED] (b)(5) I’m receiving constant updates on the situation, and I’m very confident in our ability to help protect the public health with our leaders at the helm. [PHOTO]

### Brad Kimberly

*Director, Social Media*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-1002 | Cell: [REDACTED] (b)(6)

brad.kimberly@fda.hhs.gov



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/5/2020 4:56:47 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** COV SITREP 05 FEB  
**Attachments:** 10\_2019-nCoV Outbreak\_FDA SITREP\_05 February 2020.docx  
**Importance:** High

Today's COV sit rep is attached

Internal confidential

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/6/2020 8:21:03 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Re: thank you note for EUA team--done

Heidi,  
Thank you so much. Well done.  
Steve

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Wednesday, February 5, 2020 at 4:41 PM  
**To:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>  
**Cc:** Stephen Hahn <SH1@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: thank you note for EUA team--done

Thanks Heidi!

Sent from my iPhone

On Feb 5, 2020, at 4:37 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

FYI—just confirming this has been completed.

---

**From:** Rebello, Heidi  
**Sent:** Wednesday, February 5, 2020 11:41 AM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: For your review: thank you note to EUA team

Of course, I'll make that change.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Wednesday, February 5, 2020 11:40 AM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: For your review: thank you note to EUA team

Great Heidi,

(b)(5)

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>

**Date:** Wednesday, February 5, 2020 at 11:32 AM

**To:** Stephen Hahn <SH1@fda.hhs.gov>

**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>

**Subject:** For your review: thank you note to EUA team

Attached and below is a thank you note for the EUA team. Please let me know if you have any edits. If not, we'll get this distributed on your behalf. Thank you.

**(b)(5)**

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/6/2020 1:01:48 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** 2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting  
**Start:** 2/7/2020 1:15:00 PM  
**End:** 2/7/2020 1:50:00 PM  
**Show Time As:** Busy

---

**From:** Arthur Allen [aallen@politico.com]  
**Sent:** 2/6/2020 2:15:57 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]  
**Subject:** Using off-label drugs for coronavirus treatment [from MKZ's friend Art]

Dr. Hahn,

I wonder if you could give me a picture of how the federal public health agencies are evaluating antiviral drugs for treating Wuhan coronavirus infections.

My understanding is that before FDA issues any sort of EUA for an off-label use, it would require clinical trials with at least a small placebo arm. Are trials like this being organized currently—any effort to get IRBs, etc., in place?

--I understand there are trials in China. How might data from those trials be considered here? Does FDA have any way of tracking the efficacy of these antivirals as doctors in various parts of the world start using them?

--In a worst-case scenario, if many cases of coronavirus were to start occurring in the United States, would FDA make some kind of effort to communicate about off-label uses, if there were some indication that they were at least partially efficacious?

--Also, we were curious why FDA put a notice on its website saying visitors to White Oak would get special screening. No other federal agencies seem to have done this.

Of course feel free to call me. Thanks and best regards,

Art

Arthur Allen  
Editor, eHealth+Pharma, POLITICO  
202-365-6116  
author, *Vaccine: the controversial story of medicine's greatest lifesaver* (WW Norton); *The Fantastic Laboratory of Dr. Weigl* (WW Norton)



---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/6/2020 2:17:14 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]  
**Subject:** Quick Stop-By/Thank You: 2019-nCoV Incident Management Group  
**Location:** EOC  
**Start:** 2/10/2020 4:10:00 PM  
**End:** 2/10/2020 4:20:00 PM  
**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Mair, Michael

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/6/2020 2:17:14 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HOLD: Quick Stop-By/Thank You: 2019-nCoV Incident Management Group in the EOC  
**Start:** 2/10/2020 4:10:00 PM  
**End:** 2/10/2020 4:20:00 PM  
**Show Time As:** Busy

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/6/2020 2:17:14 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HOLD: 2019-nCoV Incident Management Group in the EOC  
**Start:** 2/10/2020 4:10:00 PM  
**End:** 2/10/2020 4:20:00 PM  
**Show Time As:** Busy

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/6/2020 2:36:55 PM  
**Subject:** HOLD: nCoV Agency Executive Group meeting  
**Start:** 2/7/2020 4:30:00 PM  
**End:** 2/7/2020 5:00:00 PM  
**Show Time As:** Busy

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/6/2020 2:37:46 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]  
**Subject:** FDA Heads Up for HHS NN - 2/7/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/7/20:

- **FDA to continue to highlight actions in response to 2019-nCoV**

Tomorrow, FDA is expected to continue to communicate on its work in response to the Novel Coronavirus Outbreak (2019-nCoV).

- **Nature Biotechnology to run FDA opinion piece on regulation of Intentional Genomic Alterations (IGA) in animals**

Tomorrow, the publication Nature Biotechnology is expected to run an opinion piece by FDA on IGAs in animals. This piece will accompany a scientific article that FDA has already submitted to the publication.

- **FDA to grant marketing of first cardiac ultrasound software using AI (confidential)**

Tomorrow, FDA is expected to grant marketing authorization of the Caption Guidance software, used with compatible general-purpose diagnostic ultrasound systems, to assist medical professionals in the acquisition of cardiac ultrasound images. The software was developed using artificial intelligence/machine learning.

---

**From:** Wilson, Eric (OS/ASPR/EXSEC) [Eric.Wilson1@hhs.gov]  
**Sent:** 2/6/2020 3:19:13 PM  
**To:** ASPR Exec Sec (OS/ASPR) [ASPRExecSec@hhs.gov]  
**Subject:** Immediate Implementation of the Emergency Use Simple Letter Agreement Under the USG Sample Sharing Framework for Sharing of Material Related to 2019 Novel Coronavirus  
**Attachments:** USG Sample Sharing Framework-FINAL-signed.pdf; EUSLATEmplate\_2019-nCoV\_Final.docx  
**Flag:** Follow up

**(b)(5)**

Sincerely,

Robert P. Kadlec, MD, MTM&H, MS

Assistant Secretary for Preparedness and Response

Robert R. Redfield, M.D.

Director, U.S. Centers for Disease Control and Prevention

Administrator, Agency for Toxic Substances and Disease Registry

Attachments:

1. Emergency Use Simple Letter Agreement Template for 2019-nCoV
2. Copy of the *Operational Framework to Promote Rapid Access to Biological Material Related to non-Influenza Pathogens with the Potential to Cause a Public Health Emergency of International Concern and Facilitate its Sharing among U.S. Federal Departments and Agencies*

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/6/2020 4:51:35 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]

**CC:** Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abfb1e-KMO8]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]

**Subject:** Canceled: Canceled: nCoV Agency Executive Group meeting

**Attachments:** Untitled Attachment; Canceled: nCoV Agency Executive Group meeting

**Location:** 1-877-465-7975, code (b)(6)

**Start:** 2/7/2020 4:30:00 PM

**End:** 2/7/2020 5:00:00 PM

**Show Time As:** Free

**Importance:** High

**Recurrence:** Weekly  
every Friday from 4:30 PM to 5:00 PM

**Required Attendees:** Lenihan, Keagan; Hahn, Stephen; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Schwartz, Suzanne; Shah, Anand; Throckmorton, Douglas C; James Tyler; Clarke, Mary Beth; Malais, Tanya

AEG meetings have been established to address policy and resource issues related to the nCoV public health emergency. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

---

**From:** Solomon, Steven M [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E49AC6A056DC4F299EA269945E962E82-SSOLOMON]  
**Sent:** 2/6/2020 5:02:01 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** RE: Chinese Food Markets

thanks

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Thursday, February 6, 2020 4:42 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Chinese Food Markets

Hey there—

Below is the link re: Chinese markets that Anand had mentioned in this afternoon's meeting

<https://www.nytimes.com/2020/01/25/world/asia/china-markets-coronavirus-sars.html>

Thanks!

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/6/2020 5:05:52 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: Chinese Food Markets

Thx and very interesting

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Date:** February 6, 2020 at 4:41:48 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Chinese Food Markets

Hey there—

Below is the link re: Chinese markets that Anand had mentioned in this afternoon's meeting

<https://www.nytimes.com/2020/01/25/world/asia/china-markets-coronavirus-sars.html>

Thanks!

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/6/2020 5:22:21 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** 06 FEB SITREP  
**Attachments:** 11\_2019-nCoV Outbreak\_FDA SITREP\_06 February 2020.docx

Attached please find today's COV sit rep

Internal confidential

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/7/2020 10:41:54 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: DLG agenda  
**Attachments:** DLG TPs\_07 FEB 2020.docx

**Flag:** Follow Up

Here are talked that were flagged for the DLG meeting this afternoon. Will print off and give to Frank to make sure you have a copy when you get back to the office for when that meeting happens.

Thanks

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Thursday, February 6, 2020 2:31 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: DLG agenda

How this? Happy to change as needed – thx.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Thursday, February 6, 2020 1:03 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: DLG agenda

Thanks, Denise.

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Sent:** Thursday, February 6, 2020 1:03 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: DLG agenda

Of course – will do.

Thanks,

Denise

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Thursday, February 6, 2020 1:01 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>

**Subject:** FW: DLG agenda

Denise, can you please have someone on the OCET team draft the high-level TPs for the Commissioner to guide his 2 minute update tomorrow for the DLG (he is also going to join)? We will need to get them to him this evening so copying in Colin and Keagan for their awareness as well.

I can review the draft TPs before we send them up to the front office. Thanks in advance.

---

**From:** Abram, Anna

**Sent:** Thursday, February 6, 2020 12:59 PM

**To:** 'Wolf, Laura (OS/ASPR/SIIM)' <Laura.Wolf@hhs.gov>

**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Subject:** RE: DLG agenda

Dr. Hahn will join so Denise and I will defer to the Commissioner to provide the 2 minute update for FDA.

---

**From:** Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>

**Sent:** Thursday, February 6, 2020 11:28 AM

**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** DLG agenda

Anna-

Since the DLG is only half an hour, there are 2 minutes available for fda update (and 2 for sns and pcc as well). Whose name should we put on the agenda?

Laura Kwinn Wolf, Ph.D.

Director, Division of Critical Infrastructure Protection

HHS/ASPR

Unclassified: Laura.wolf@hhs.gov

HSDN: Laura.wolf@dhs.gov

Desk: 202-260-0666

Cell: (b)(6)

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/7/2020 10:52:46 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HHS Press Conference (arrive 1:45 pm - sit in the front row; begins at 2:00 pm)  
**Location:** HHS Small Auditorium  
**Start:** 2/7/2020 1:45:00 PM  
**End:** 2/7/2020 2:30:00 PM  
**Show Time As:** Busy

Today at 2pm, there will be a press conference in the HHS small auditorium on the Coronavirus. We ask that your principals please attend and sit in the front row. They may be asked to answer questions that pertain to their portfolios.

**We have not advised the event yet and will forward once the advisory goes out.**

Please have your principal arrive by no later than 1:45 PM.

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/7/2020 10:52:46 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HOLD: HHS Press Conference (arrive 1:45 pm - sit in the front row; begins at 2:00 pm)  
**Location:** HHS Small Auditorium  
**Start:** 2/7/2020 1:45:00 PM  
**End:** 2/7/2020 2:30:00 PM  
**Show Time As:** Busy

Today at 2pm, there will be a press conference in the HHS small auditorium on the Coronavirus. We ask that your principals please attend and sit in the front row. They may be asked to answer questions that pertain to their portfolios.

**We have not advised the event yet and will forward once the advisory goes out.**

Please have your principal arrive by no later than 1:45 PM.



---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/7/2020 3:06:04 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]  
**Subject:** FDA Heads Up for HHS NN - 2/10/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/10/20:

- **FDA to put forth fiscal year 2021 budget request as part of President's budget (confidential)**  
As part of the President's fiscal year (FY) 2021 budget request, on Monday FDA is expected to request \$6.2 billion to focus on five strategic priorities: reduce the burdens of addiction crises; leverage innovation and competition; empower and protect consumers and patient's safety; assure public health through emerging technologies; and invest in a next generation expert workforce and the improvement of infrastructure.
- **FDA to continue to provide updates in response to 2019-nCoV**  
On Monday, FDA is expected to continue to communicate on its work in response to the Novel Coronavirus Outbreak (2019-nCoV).
- **FDA to announce upcoming for patient-focused drug development for vitiligo**  
On Monday, FDA is expected to announce a March 30 public meeting to obtain patient perspectives on the impact of vitiligo on daily life, patient views on treatment approaches, and decision factors considered when selecting a treatment.

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/7/2020 4:38:20 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** 07 Feb FDA Sitrep  
**Attachments:** 12\_2019-nCoV Outbreak\_FDA SITREP\_07 February 2020.docx

Today's COV sit rep is attached.

Internal confidential

---

**From:** Kimberly, Brad [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08BC909ED76D49868A5FF92C3C70FB72-BRADLEY.KIM]  
**Sent:** 2/7/2020 5:46:22 PM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]  
**Subject:** RE: PLEASE HOLD RE: TWEETS for REVIEW: Coronavirus Presser

Holding.

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs  
Office of External Affairs

U.S. Food and Drug Administration

Tel 240-402-1002 | Cell: (b)(6)

brad.kimberly@fda.hhs.gov



---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Friday, February 7, 2020 5:46 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** PLEASE HOLD RE: TWEETS for REVIEW: Coronavirus Presser

Please HOLD

**Laura M. Caliguiri**

*Associate Commissioner, Office of External Affairs*



---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Friday, February 7, 2020 5:43 PM  
**To:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** Re: TWEETS for REVIEW: Coronavirus Presser

Good to go! Thanks!

---

**From:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Date:** February 7, 2020 at 5:30:14 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** TWEETS for REVIEW: Coronavirus Presser

Good evening... this a tweet thread based on today's press conference... for your review. Thanks! --Brad

===

(b)(5)

5. This week the FDA also issued an EUA to the @CDCgov for the first novel #coronavirus diagnostic. Being able to identify #2019nCoV cases is a critical step in the response efforts to support patients in need of care & mitigate further spread of the virus. <https://go.usa.gov/xd8b3> [1st EUA graphic]

6. Here at FDA, we are fully engaged with our experts participating in USG response efforts to develop vaccines & therapeutics for novel #coronavirus and are working closely with our government and international partners.

7. We are meeting with any sponsor interested in developing vaccines and therapeutics designed to protect against or treat the 2019 novel coronavirus. #2019nCoV

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-1002 | Cell: (b)(6)

[brad.kimberly@fda.hhs.gov](mailto:brad.kimberly@fda.hhs.gov)



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/7/2020 6:46:05 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Updated CoV sit rep 2/7/20  
**Attachments:** 12\_2019-nCoV Outbreak\_FDA SITREP\_07 February 2020.docx

Attached. CDRH has a tweak after it was sent.

Internal confidential

---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/8/2020 9:12:37 AM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]  
**Subject:** Re: WaPo CoV zoonotic disease article

Thanks Anna. Steve Solomon, Bernadette Dunham and I have been discussing zoonotic infections at our One Health meetings, which definitely warrants more attention.

<https://www.fda.gov/animal-veterinary/animal-health-literacy/one-health-its-all-us>

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** February 8, 2020 at 8:52:13 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Subject:** WaPo CoV zoonotic disease article

FYI

## Health

### Coronavirus came from bats or possibly pangolins amid 'acceleration' of new zoonotic infections

Joel Achenbach

Feb. 7, 2020 at 1:01 p.m. EST

The outbreak of a new kind of coronavirus in central China is loaded with mysteries, and among the biggest is how the virus made the jump from an animal host into humans. This global health crisis is a reminder of the danger of zoonosis — the ability of pathogens, including bacteria and viruses, to enter the human population from an animal host.

The coronavirus is similar to two viruses that circulate in bats, but it might have skipped through another species before infecting humans.

Suspicion has fallen on the pangolin, an endangered, highly trafficked creature that looks like a cross between an anteater and an armadillo. Its scales are prized in traditional Chinese medicine, although they are made of keratin, just like fingernails. In recent days some researchers have noted that a coronavirus previously identified in pangolins is more closely related to the novel coronavirus than any virus identified so far.

AD

It is not clear whether any bats or pangolins, live or dead, were on sale in December at the Huanan Seafood Wholesale Market in Wuhan, where more than half of the people first identified with the virus had shopped. And it is possible that the viral leap into humans occurred somewhere else, as some early cases occurred in people with no known link to it.

The disease detectives need to nail down the host species because there could be a population of animals capable of sparking new outbreaks, said Melissa Nolan, an infectious-disease epidemiologist at the University of South Carolina.

“If we don’t know what the intermediate host is and it’s clearly capable of transmitting this infection, then we ultimately can’t stop the spread of this virus,” she said.

AD

The World Health Organization has declared a public health emergency because of the outbreak, which has sickened more than 30,000 people, killing more than 630, mostly in China. The virus appears to be sufficiently contagious to become a global pandemic if not contained. It remains unclear whether the virus can be transmitted by infected people before they show symptoms.

In recent days scientists have wrestled with the sticky question of what to call the new coronavirus. Right now it is officially “2019-nCoV,” which is inelegant at best and does little to describe the virus or the resulting disease in humans. One possibility is that the virus will be given a name that is a variant of SARS (sudden acute respiratory syndrome), a virus that killed 774 people in 37 countries before it was contained. The two coronaviruses are very similar genetically, and both are found in bats.

*These bats carry the lethal Marburg virus, and disease detectives are tracking them to stop its spread*

“They likely had a common ancestor in the bat population,” said Stanley Perlman, a virologist at the University of Iowa who is part of the Coronavirus Study Group, a subset of the International Committee on the Taxonomy of Viruses.

AD

“It’s like a cousin,” he said. “They probably started from a common ancestor some years ago in bats, and they mutated and evolved, and that’s what you have now.”

He said the committee favors including SARS in the name of the new virus.

“It’s close to SARS. But it’s not SARS. You could say a SARS-like virus, slash Wuhan, slash 2019,” he said. “From a taxonomic point of view, it’s so related to the previous virus, it needs to be included in its name.”

After the emergence of Middle East respiratory syndrome (MERS) in Saudi Arabia in 2012, the WHO in 2015 asked national authorities, scientists and the news media to not name a virus after people, a geographic location, a cultural group or even a species of animal, because that can stigmatize communities or incite needless slaughtering of animals.

AD

Scientists have identified about 400 emerging diseases since 1940, and more than 6 out of 10 have been zoonotic, according to a 2012 study published in the Lancet, a British medical journal. They include HIV from chimpanzees, Ebola and Marburg from bats, hantavirus from mice, MERS from camels, and swine flus and avian flus. Bats make up roughly a fifth of all mammal species and are frequent reservoirs of viruses that can potentially infect humans.

“We only know a really small fraction of the viruses that exist in wild animal populations. We’ve really just scratched the surface,” said Christine Johnson, an epidemiologist at the University of California at Davis whose research has helped identify scores of coronaviruses in wild animals in Asia and Africa.

This “spillover” happens unpredictably. It is unclear why and how a virus that normally replicates in an animal starts to infect humans. No epidemic zoonotic disease in history has been predicted before the viral leap.



“Why it’s occurring now is really a mystery,” Perlman said. “You have people being around bats forever, eating bats and buying them in markets. Why did it take until December 2019?”

If the species that facilitated the jump from bats to humans is really a pangolin, that could complicate the search for its origins, said Benjamin Neuman, a virologist at Texas A&M University at Texarkana who is also in the Coronavirus Study Group. “If the illegal animal trade was at the root of this outbreak, it is going to be really difficult to trace, and I suspect most of the evidence is gone already — destroyed or spread out across the black market,” he said. “People aren’t going to want to talk, because of the consequences.”

In late December, four patients turned up ill in a hospital in Wuhan. Each had pneumonia-like symptoms and fever, and they tested negative for known diseases. Chinese authorities were on the lookout for a mystery illness such as this one, because they had seen it 17 years ago, when SARS flared in Guangdong province.

---

AD

Life on Earth exists in a thick microbial soup. Survival typically requires collaboration with symbiotic organisms (for example, gut bacteria in humans) and the forbearance of potentially lethal pathogens. Few things are more enigmatic than viruses, which are just bare-bones strips of genetic material, either DNA or RNA, with some kind of protective coating.

On their own, outside a cell, viruses don’t do anything at all. They have no metabolism, no motion, no ability to reproduce. Scientists debate whether viruses, when outside a host, meet the standard for being alive. To reproduce, a virus has to enter the cell of a living host and hijack that cell’s machinery to make more of the virus.

“It’s switching between alive and not alive in its existence,” said Gary Whittaker, a Cornell University professor of virology, describing a virus as being somewhere “between chemistry and biology.”

---

AD

Although the phenomenon of zoonosis has been happening among human beings and the animals they encounter for untold thousands of years, the modern world has made zoonotic epidemics more likely to occur, experts say. It’s a matter of numbers and geography. More people are coming into contact with more animals in more places, including habitats rarely or never visited by human beings — such as bat caves deep within a forest.

“We’re absolutely seeing an acceleration in the emergence of zoonotic disease,” said Jonathan Epstein, an epidemiologist at EcoHealth Alliance, a nonprofit group that studies emerging infectious diseases.

Changes in land use — agriculture, mining, etc. — play a huge role in creating opportunities for viral jumps. So do wild-animal markets. Authorities in China cracked down on sales of wild animals after SARS was linked to masked palm civets, catlike mammals. China later backed off some of the restrictions. Wild-animal markets remain common in much of the world.

---

AD

Once a virus jumps into humans, population density becomes a factor in turning what might potentially be a small eruption of illnesses into an epidemic. A crowded city such as Wuhan, which has a population on the same order of magnitude as New York or London, creates conditions for person-to-person transmission.

Because these events have remained unpredictable, the public health responses have tended to be a game of catch-up, with communities desperately trying to contain the spread of the virus through quarantines, disease surveillance and rigorous hygiene practices. Eventually a vaccine can provide broad protection, but development takes many months or years.

Viruses have differing levels of contagiousness and virulence (the degree to which they make someone sick). The reproduction rate — how many people a sick person is likely to infect, on average — helps determine how widely it will spread. In a study in the Lancet, three University of Hong Kong scientists estimated that the coronavirus has a reproduction rate of 2.68, meaning every 10 sick people would eventually infect approximately 27 others.

“On the present trajectory [the coronavirus] could be about to become a global epidemic in the absence of mitigation,” the report states. To prevent a large epidemic outside the city of Wuhan, “substantial, even draconian measures that limit population mobility should be seriously and immediately considered in affected areas,” along with school closures and cancellation of mass gatherings, the authors state.

Global trade is a force multiplier for viruses. Viruses are not terribly stable outside a host, but if they can latch onto a globe-trotting species, they can go everywhere.

There are contradictory incentives for the virus. If it makes a person very sick and symptomatic — coughing, sneezing, throwing up, etc. — that can enhance the spread of the virus. But a sick person tends to be immobile and isolated and in contact with fewer people. A milder disease can spread more easily. Highly lethal viruses tend to burn themselves out quickly because there is no one left alive to spread them.

Transmission from one person to another usually requires a lot of the virus, said Nolan, the University of South Carolina epidemiologist.

“Our immune system does a good job of stopping infection in our body,” she said. “There’s a certain number when that pathogen can take over. Think about a mob. One person in the street probably can’t topple a car, but if you had a 100 people in the street, they could probably push a car over if they’re angry enough.”

Out of control: How the world’s health organizations failed to stop the Ebola disaster

What life is like for U.S. coronavirus evacuees under quarantine

We are swimming in a sea of viruses

## What you need to know about coronavirus

Updated February 7, 2020

**Follow our updates:** Chinese health officials say they confirmed more than 31,000 cases of the novel coronavirus, more than 4,800 of them considered severe. The death toll surpassed 630.

Meanwhile, **quarantined on military bases, U.S. evacuees** resort to Zumba, stairwell races and accounting classes.

**Chinese doctor Li Wenliang**, who became a symbol of the Chinese government’s failings after sounding warnings about the disease in December, **died Thursday after contracting the virus in Wuhan**. Within hours of his death, millions of Chinese tried to bypass censors to post the hashtag “We demand freedom of speech.”

**Are you in isolation or quarantine because of the coronavirus? We want to hear about it.** Have you seen or experienced any discrimination, racism or xenophobia connected to the ongoing coronavirus epidemic? **Share your story.**

**Mapping the spread of the new coronavirus:** The United States, Germany, Sri Lanka, France, Cambodia, the Philippines, India, Thailand, Japan, Nepal, Hong Kong, Singapore, the United Arab Emirates, Canada, Vietnam, Macao and South Korea have all confirmed cases of the infection.

**What is coronavirus and how does it spread?** Coronaviruses are a large family of viruses whose effects range from causing the common cold to triggering much more serious diseases, such as severe acute respiratory syndrome, or SARS. **Here’s what we know so far.**

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/8/2020 10:07:08 AM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]  
**Subject:** Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

JAMA: [Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China](#)

**Conclusions and Relevance** In this single-center case series of 138 hospitalized patients with confirmed NCIP in Wuhan, China, presumed hospital-related transmission of 2019-nCoV was suspected in 41% of patients, 26% of patients received ICU care, and mortality was 4.3%.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/9/2020 8:56:24 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: nCoV Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: (b)(6) or COO Conference Room (WO2/3305)  
**Start:** 2/6/2020 5:15:00 PM  
**End:** 2/6/2020 5:45:00 PM  
  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/9/2020 9:01:35 AM  
**To:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]  
**CC:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]  
**Subject:** Re: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

Thanks, Michael. Very interesting.

---

**From:** "Mair, Michael" <Michael.Mair@fda.hhs.gov>  
**Date:** Saturday, February 8, 2020 at 10:07 AM  
**To:** Anna Abram <Anna.Abram@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Steven Solomon <Steven.Solomon@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Stacy Amin <Stacy.Amin@fda.hhs.gov>, Erika Anderson <Erika.Anderson@fda.hhs.gov>, Denise Hinton <Denise.Hinton@fda.hhs.gov>, Peter Marks <Peter.Marks@fda.hhs.gov>, "Farley, John" <John.Farley@fda.hhs.gov>, "Schwartz, Suzanne" <Suzanne.Schwartz@fda.hhs.gov>  
**Subject:** Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

JAMA: Clinical Characteristics of 138 Hospitalized Patients With 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China

**Conclusions and Relevance** In this single-center case series of 138 hospitalized patients with confirmed NCIP in Wuhan, China, presumed hospital-related transmission of 2019-nCoV was suspected in 41% of patients, 26% of patients received ICU care, and mortality was 4.3%.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/9/2020 9:52:17 AM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: FDA Communications Forecast (Mon., Feb. 10 - Fri., Feb. 21)  
**Attachments:** FDA Communications Forecast\_2.21.20.docx

Laura,  
I think Amy's suggestion is a good one and I'd like to proceed as she suggests. Would you facilitate?  
Thanks  
Steve

---

**From:** Amy Abernethy <Amy.Abernethy@fda.hhs.gov>  
**Date:** Friday, February 7, 2020 at 2:19 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** FW: FDA Communications Forecast (Mon., Feb. 10 - Fri., Feb. 21)

Hi – I was looking at the planned Comms. (b)(5)

(b)(5)

Cheers-  
A

---

**From:** "Saghafi, Michelle" <Michelle.Saghafi@fda.hhs.gov>  
**Date:** Friday, February 7, 2020 at 1:14 PM  
**To:** OC-Executive Secretariat-Policy Analysts <OC-ExecutiveSecretariat-PolicyAnalysts@fda.hhs.gov>, OEA External Communications <OEAExternalCommunications@fda.hhs.gov>  
**Subject:** FDA Communications Forecast (Mon., Feb. 10 - Fri., Feb. 21)

Please find attached the FDA Communications Forecast for the next two weeks (Mon., Feb. 10 - Fri., Feb. 21).

As a reminder, it contains commercial confidential information.

Best,

Michelle

**Michelle A. Saghafi, MBA**  
*Public Affairs Specialist*

Office of Editorial and Creative Services  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 301-796-8628 / Cell: (b)(6)  
michelle.saghafi@fda.hhs.gov



---

**From:** Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]  
**Sent:** 2/9/2020 1:51:16 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: Murphy/Rubio letter

You're welcome

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Sunday, February 9, 2020 1:39 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>  
**Subject:** RE: Murphy/Rubio letter

Thx Denise

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Date:** February 9, 2020 at 1:11:26 PM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>  
**Subject:** RE: Murphy/Rubio letter

Thanks - all Centers/ORAs are represented on IMG. We'll work together to provide an informative response as we continue to assess our opportunities and mitigate risks.

Thanks,  
Denise

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Sunday, February 9, 2020 10:14 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>  
**Subject:** Re: Murphy/Rubio letter

And after skimming letter would add that (b)(5)  
(b)(5) Thanks!

Off line for next hour and then back online for today.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Date:** February 9, 2020 at 10:11:30 AM EST



**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Subject:** Re: Murphy/Rubio letter

Thanks, all, for working with and through IMG so we are fully in sync.

Plus Denise and Michael.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** February 9, 2020 at 9:50:25 AM EST  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: Murphy/Rubio letter

Thanks

---

**From:** Karas Gross <Karas.Gross@fda.hhs.gov>  
**Date:** Sunday, February 9, 2020 at 9:48 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Maren McBride <Maren.McBride@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Murphy/Rubio letter

Our teams are working the letter and response through the IMG now and aim to meet the 2/18 deadline in the letter. Happy to discuss further.

Karas

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Sunday, February 9, 2020 9:37 AM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Murphy/Rubio letter

Good morning Karas and Maren,  
I'd like to be able to respond to this query fairly quickly given the rapidly evolving situation. Let's discuss. Anand, would you discuss some of the specifics with CDER and CBER?

Thanks.

Steve

<https://www.murphy.senate.gov/newsroom/press-releases/murphy-rubio-urge-fda-to-ensure-the-safety-and-supply-of-pharmaceuticals-food-and-medical-supplies-amid-growing-coronavirus-epidemic>

---

**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 2/9/2020 2:42:29 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Patel, Chaitali [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815d91f3d5e143b387acd82539f7e149-Chaitali.Pa]  
**Subject:** RE: Murphy/Rubio letter

Yes – and will coordinate with IMG

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Sunday, February 9, 2020 9:37 AM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Murphy/Rubio letter

Good morning Karas and Maren,  
I'd like to be able to respond to this query fairly quickly given the rapidly evolving situation. Let's discuss. Anand, would you discuss some of the specifics with CDER and CBER?  
Thanks.  
Steve

<https://www.murphy.senate.gov/newsroom/press-releases/murphy-rubio-urge-fda-to-ensure-the-safety-and-supply-of-pharmaceuticals-food-and-medical-supplies-amid-growing-coronavirus-epidemic>

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/9/2020 6:23:39 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** Telecon: Coronavirus Check-In  
**Location:** 1-877-465-7975,, (b)(6)

**Start:** 2/10/2020 8:30:00 AM  
**End:** 2/10/2020 9:00:00 AM  
**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan; Anna Abram; Stacy Amin; Shah, Anand; Rom, Colin

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/9/2020 7:19:52 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]  
**Subject:** Fwd: WHO advance team on coronavirus on way to China - Tedros tweet

FYI. Close hold.

---

**From:** Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>  
**Date:** February 9, 2020 at 6:34:52 PM EST  
**To:** Fauci, Anthony S (NIH) [REDACTED], Harrison, Brian (OS) <Brian.Harrison@hhs.gov>  
**Cc:** Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>, Elvander, Erika (OS) <Erika.Elvander@hhs.gov>, Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>, Redfield, Robert R (CDC) [REDACTED], Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>  
**Subject:** RE: WHO advance team on coronavirus on way to China - Tedros tweet

Dr F,

(b)(5)

---

**From:** Fauci, Anthony (NIH/NIAID) [E] [REDACTED]  
**Sent:** Sunday, February 9, 2020 6:24 PM  
**To:** Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>  
**Cc:** Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Redfield, Robert R. (CDC/OD) [REDACTED]; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>  
**Subject:** RE: WHO advance team on coronavirus on way to China - Tedros tweet

I do not like the sound of this. So now we are in the cueue with other countries? Seems like he is talking about at best 1 USA person and maybe even 0 USA people.

Anthony S. Fauci, MD  
Director  
National Institute of Allergy and Infectious Diseases

(b)(6)

(b)(6)

National Institutes of Health

Bethesda, MD 20892-2520

Phone (b)(6)

FAX: (301) 496-4409

E-mail: (b)(6)

The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

---

**From:** Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>

**Sent:** Sunday, February 9, 2020 6:03 PM

**To:** Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>

**Cc:** Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Redfield, Robert R. (CDC/OD) (b)(6) <@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E (b)(6)]; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

**Subject:** FW: WHO advance team on coronavirus on way to China - Tedros tweet

Brian – more clarity from “the horse’s mouth” on this advance trip...see below.

---

**From:** Grigsby, Garrett (HHS/OS/OGA)

**Sent:** Sunday, February 9, 2020 6:01 PM

**To:** SCHWARTLANDER, Bernhard F. <schwartzlanderb@who.int>

**Cc:** SIMONSON, Stewart <simonsons@who.int>

**Subject:** RE: WHO advance team on coronavirus on way to China - Tedros tweet

Many thanks, Bernard! I know I’ll be asked, so I will pass your email up the chain...

Take care and thanks again!

---

**From:** SCHWARTLANDER, Bernhard F. <schwartzlanderb@who.int>

**Sent:** Sunday, February 9, 2020 5:59 PM

**To:** Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>

**Cc:** SIMONSON, Stewart <simonsons@who.int>

**Subject:** Re: WHO advance team on coronavirus on way to China - Tedros tweet

Hi Garrett,

We have three people on the way to Beijing who will work with our Chinese counterparts on finalizing the TOR and composition of the joint WHO - China mission. As you are much aware, the US has given us a number of names who will be able and willing to join such a mission. We have received similar proposals from other countries and will now match the “long list” of experts with the required specific expertise.

We are hoping to have more clarity over the coming days and will obviously keep you in the loop. The overall number will be kept at a level to make sure that the team is fully operational.

With my warmest wishes

Bernhard

Dr Bernhard Schwartländer  
Chef de Cabinet  
World Health Organization

On 9 Feb 2020, at 23:24, Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov> wrote:

Bernard,

Hope you had a good weekend.

I'm reaching out to get more clarity on the WHO experts team issue – please see article below. I've heard everything from an advance group of one or two individuals to 15 people discussed in the article. I haven't heard any word about US people, and I was just with Dr Redfield late this afternoon and he was in the dark too.

Any additional information will be deeply appreciated.

Thanks!

---

**From:** Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>

**Sent:** Sunday, February 9, 2020 5:03 PM

**To:** Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>; Tracy Carson <CarsonTL@state.gov>

**Subject:** WHO advance team on coronavirus on way to China - Tedros tweet

February 9, 2020 / 4:01 PM / Updated an hour ago

## **UPDATE 1-WHO advance team on coronavirus on way to China - Tedros tweet**

Stephanie Nebehay

By Stephanie Nebehay

GENEVA, Feb 9 (Reuters) - An advance team of international experts led by the World Health Organization (WHO) has left for Beijing to help investigate China's coronavirus epidemic, the Geneva-based agency said on Sunday.

WHO director-general Tedros Adhanom Ghebreyesus, who made a trip to Beijing for talks with President Xi Jinping and Chinese ministers in late January, returned with an agreement on sending an international mission.

But it has taken nearly two weeks to get the government's green light on its composition, which was not announced, other than to say that WHO veteran Dr. Bruce Aylward, a Canadian epidemiologist and emergencies expert, was heading it.

"I've just been at the airport seeing off members of an advance team for the @WHO-led #2019nCoV international expert mission to #China, led by Dr Bruce Aylward, veteran of past public health emergencies," Tedros said in a tweet from Geneva.

Dr. Sylvie Briand, who accompanied Tedros last month and stayed behind for talks with top Chinese health officials, told Reuters last week that they were discussing a list of experts with China.

“Because it is a joint mission, they need to be on board, it’s not just an international group going there. We have about 15 people,” said Briand, director of Global Infectious Hazard Preparedness at WHO.

China raised the death toll from the coronavirus outbreak to 811 on Sunday, passing the number killed globally by the SARS epidemic, as authorities made plans for millions of people returning to work after an extended Lunar New Year break.

The virus, which has spread to two dozen countries, has killed some 2% of more than 37,550 cases worldwide, with 99 percent of infections in China, WHO figures show.

The WHO declared the outbreak a global emergency on Jan. 30, days after the Chinese central government imposed a lockdown on 60 million people in Hubei province and its capital Wuhan, epicentre of the virus that emerged in December in a seafood market.

Tedros said on Saturday that he hoped the team would include experts from the U.S. Centers for Disease Control (CDC). “It has to be meaningful on the ground,” Lawrence Gostin, professor of global health law at Georgetown Law, said in an interview in Geneva this week.

Gostin called for a “genuine partnership with transparent flows of information and accountability for the response”, adding that there should be a strong CDC presence.

“CDC has got no peer in terms of its experience and technical expertise in dealing with international outbreaks,” he said. “But the other benefit is the smart diplomacy, what it could signal is that despite all of our differences in ideology, trade, politics, that when faced with a common threat to humanity, we come together as a human community to tackle it,” Gostin said.

Reporting by Stephanie Nebehay; Editing by Pravin Char, Kirsten Donovan  
Our Standards: The Thomson Reuters Trust Principles.

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/10/2020 8:29:22 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Caligui, Laura (Laura.Caligui@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group



---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]

**Subject:** Commissioner Prep: Murder Board (E&C Hearing Sidecar on Coronavirus )  
**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 2/24/2020 4:00:00 PM  
**End:** 2/24/2020 5:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/10/2020 8:29:22 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]

**Subject:** Commissioner Prep: Murder Board (E&C Hearing Sidecar on Coronavirus)

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 2/24/2020 4:00:00 PM

---

**End:** 2/24/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin; Carly McWilliams; Janik, Heather; McSeveney, Megan; Anderson, Erika; Steven Solomon

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/10/2020 2:33:19 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: Materials for Hahn for WH mtg this afternoon  
**Attachments:** Considerations in coronavirus vaccine development 013120.docx; Vaccines-1-pager v3.docx; 2019\_nCoV\_Tx\_One\_Pager\_CLEAN.docx; CoV Diagnostics USG Interagency One-pager \_v7.1.docx; FDA Supply Chain Talking Points WH 2.10.20 FINAL.docx  
**Importance:** High

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Monday, February 10, 2020 1:59 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** RE: Materials for Hahn for WH mtg this afternoon  
**Importance:** High

Hi.

Attached are supply chain talking points.

Also attached are considerations for vaccine development (developed by CBER) and one-pagers developed by BARDA (cleared through interagency) on the vaccine, therapeutic, and diagnostic landscape.

Let me know if you need additional info. Thx -m

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Monday, February 10, 2020 1:19 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Materials for Hahn for WH mtg this afternoon

I know you guys are going around the clock, but do you have an update on these materials? I know we have SCIF meeting in 15 minutes so want to make sure we can keep things moving forward. Also, I know Emily was scrubbing the MCM horizon document for ethics over the past day so we need to make sure he has seen what was previously shared with the WH thru BARDA just in case that comes up (if possible).

Thanks,  
Anna

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/10/2020 3:15:58 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: Materials for Hahn for WH mtg this afternoon

The docs have marked where commercial confidential info that cannot be shared but is included for his background and list not for distr<sup>†</sup> (b)(5) †

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, February 10, 2020 3:13 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: Materials for Hahn for WH mtg this afternoon

Can he share all of this info with WH? Sharing this means it likely gets out, if we don't want it out there we should be careful what we share.

Sent from my iPhone

On Feb 10, 2020, at 2:33 PM, Rom, Colin <Colin.Rom@fda.hhs.gov> wrote:

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Sent:** Monday, February 10, 2020 1:59 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** RE: Materials for Hahn for WH mtg this afternoon  
**Importance:** High

Hi.

Attached are supply chain talking points.

Also attached are considerations for vaccine development (developed by CBER) and one-pagers developed by BARDA (cleared through interagency) on the vaccine, therapeutic, and diagnostic landscape.

Let me know if you need additional info. Thx -m

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Sent:** Monday, February 10, 2020 1:19 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Materials for Hahn for WH mtg this afternoon

I know you guys are going around the clock, but do you have an update on these materials? I know we have SCIF meeting in 15 minutes so want to make sure we can keep things moving forward. Also, I know Emily was scrubbing the MCM horizon document for ethics over the past day so we need to make sure he has seen what was previously shared with the WH thru BARDA just in case that comes up (if possible).

Thanks,

Anna

<Considerations in coronavirus vaccine development 013120.docx>

<Vaccines-1-pager v3.docx>

<2019\_nCoV\_Tx\_One\_Pager\_CLEAN.docx>

<CoV Diagnostics USG Interagency One-pager \_v7.1.docx>

<FDA Supply Chain Talking Points WH 2.10.20 FINAL.docx>

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/10/2020 5:14:52 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]  
**Subject:** FW: FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

I will forward under separate cover to other colleagues – see commentary on FDA involvement in task force and response efforts below

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Monday, February 10, 2020 4:22 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FYI For Coronavirus, US FDA Is At The Podium But Not On The Task Force

# For Coronavirus, US FDA Is At The Podium But Not On The Task Force

- 09 Feb 2020
- ANALYSIS



Derrick Gingery @dgingery [derrick.gingery@informa.com](mailto:derrick.gingery@informa.com)

## Executive Summary

The FDA is curiously not one of the HHS entities coordinating the US response to the outbreak, but must monitor for manufacturing disruptions and shortages, as well as approve new treatments and diagnostics.



Source: Screenshot of HHS webcast US FDA COMMISSIONER STEPHEN HAHN SPEAKS DURING AN HHS BRIEFING ABOUT CORONAVIRUS ON 7 FEBRUARY 2020. HE WAS CALLED UP FROM THE AUDIENCE TO ADDRESS MANUFACTURING ISSUES SINCE FDA IS NOT PART OF THE ADMINISTRATION'S TASK FORCE CHARGED WITH RESPONDING TO THE OUTBREAK.

The US response to coronavirus does not necessarily have the Food and Drug Administration sitting at the coordinating table, despite its key role in fighting and containing the outbreak.

However, like the most recent press conference on the subject, the FDA will be called up to offer its expertise.

## President Trump's Coronavirus Task Force

- Alex Azar, HHS Secretary
- Robert O'Brien, assistant to the president for national security affairs
- Robert Redfield, CDC director
- Anthony Fauci, NIH National Institute of Allergy and Infectious Diseases director
- Stephen Biegun, State Department Deputy Secretary
- Ken Cuccinelli, Homeland Security Department acting deputy secretary
- Joel Szabat, Transportation Department acting under secretary for policy
- Matthew Pottinger, assistant to the president and deputy national security advisor



- Rob Blair, assistant to the president and senior advisor to the Chief of Staff
- Joseph Grogan, assistant to the president and director of the Domestic Policy Council
- Christopher Liddell, assistant to the president and deputy chief of staff for policy coordination
- Derek Kan, executive associate director, Office of Management and Budget

FDA Commissioner Stephen Hahn stepped into the coronavirus spotlight on 7 February, appearing at a press conference with Health and Human Services Secretary Alex Azar and others. Hahn was not on stage with coronavirus task force members, but was called up from the audience to respond to a question about the medical product supply chain. Hahn said that to date there have been no reports of disruptions related to facilities in China, the center of the outbreak.

“FDA is closely monitoring the situation,” he said. “We're working with our government collaborators as well as manufacturers to monitor what's going on in the supply chain. At this moment we have received no reports from manufacturers about disruptions to the medical product supply chain. Obviously, the situation is fluid and we'll do everything we can to continue to monitor this and act accordingly.”

The comments largely follow earlier assurances from the agency's drug shortage team that so far, the coronavirus (also known as 2019-nCoV) outbreak is not causing problems for the US drug supply. (Also see "Coronavirus Not Impacting Rx Manufacturing Supply Chain – Yet" - Pink Sheet, 29 Jan, 2020.)

The agency has discussed its activities since the outbreak began, created a website with updates and resources, but was not included on President Trump's coronavirus task force. The 12 spots were given to Azar, Centers for Disease Control and Prevention Director Robert Redfield, National Institute of Allergy and Infectious Diseases Director Anthony Fauci, and others. (*See box.*)

The FDA, HHS and White House would not explain why the FDA was not a member of the task force. The move seemed a bit odd, given that the FDA's role in the response. The agency already has provided an emergency use authorization for a CDC coronavirus diagnostic and is helping streamline the development of vaccines and other countermeasures.

The reason may be that there simply were not enough seats at the President's table. Anand Parekh, chief medical advisor at the Bipartisan Policy Center, told the *Pink Sheet* that HHS likely has its own intra-department leadership team that includes Hahn.

And while the response to the outbreak should not be distracted by jockeying for screen time, from a strictly logistical perspective, keeping the FDA in the loop would seem to be warranted. Indeed, even without a seat at the task force table, FDA will have close to the first and last word in the government's response to the outbreak – from authorizing the initial diagnostic to eventually, everyone hopes, approving a vaccine.

The coronavirus outbreak is among Hahn's first high-profile public appearances since taking office in December. (Also see "New US FDA Commissioner Stephen Hahn Heads to White Oak Under Vaping Cloud" - Pink Sheet, 12 Dec, 2019.) While he has conducted media interviews and given speeches internally, Hahn has not spent a lot of time in public view so far. (Also see "Hahn's Priorities For US FDA Eschew Hot-Button Issues, Focus on Traditional Themes" - Pink Sheet, 30 Jan, 2020.)

## **Treatment Could Reach Phase I In Two Months, Fauci Says**

Aside from providing the EUA for the first coronavirus diagnostic, the FDA also soon could be monitoring and preparing for clinical trial results for a treatment.

Fauci said during the press conference that a randomized control trial comparing treatment with Gilead Sciences Inc.'s antiviral remdesivir plus the standard of care to remdesivir alone has started in China.

Moderna Inc. also is developing a messenger RNA vaccine against the coronavirus. (Also see "Coronavirus Efforts Could Benefit From Little-Used Medical Countermeasures Incentives" - Pink Sheet, 29 Jan, 2020.)

Fauci said so far there have been no glitches in efforts to insert the necessary gene into the messenger RNA and use it in an animal model. He said if all continues to go well, Phase I trials in humans could begin in two months.

In addition, GlaxoSmithKline PLC is lending adjuvant expertise to the Coalition for Epidemic Preparedness Innovations, a Norwegian public-private organization, to aid vaccine development. (Also see "GSK Joins Race To Tackle Coronavirus" - Scrip, 3 Feb, 2020.)

## **FDA Increasing Visitor Scrutiny**

While the government is enforcing travel restrictions to contain the virus' spread into the US, the FDA is warning that its visitors also may face scrutiny.

The agency wrote on its website that because of the public health emergency, "visitors to FDA campuses and buildings may be asked questions related to recent international travel."

The virus is not an immediate threat in the US, but the statement suggests that sponsors may have to closely scrutinize the representatives they chose to send to the FDA headquarters in Maryland for in-person meetings.

In addition, the US has offered to send a team of experts to China to assist in their response and learn more about the virus. Azar said the Chinese government has not decided whether it will allow them there, although he expects eventually access will be granted.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/10/2020 7:14:28 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: nCoV Agency Executive Group meeting - Note time change  
**Location:** 1-877-465-7975, code (b)(6) or COO Conference Room (WO2/3305)  
**Start:** 2/10/2020 5:30:00 PM  
**End:** 2/10/2020 6:00:00 PM  
  
**Recurrence:** (none)

---

**From:** Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109E347D6AC4]  
**Sent:** 2/11/2020 12:24:00 AM  
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**Subject:** Commissioner Briefing: 2019-nCoV Agency Executive Group (supply chain issues)  
**Location:** White Oak 1/2102 or 1-877-465-7975,,, 15598371#  
**Start:** 2/11/2020 4:30:00 PM  
**End:** 2/11/2020 5:30:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Anderson, Erika; Abdoo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Randall Lutter; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth

Your meeting was found to be out of date and has been automatically updated.

---

Sent by Microsoft Exchange Server

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/11/2020 2:43:46 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]  
**Subject:** FDA Heads Up for HHS NN - 2/12/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/12/20:

- **FDA to request voluntary withdrawal of weight-loss medication (confidential)**

Today or tomorrow, FDA is expected to request that the drug manufacturer (Eisai Inc.) voluntary withdraw Belviq and Belviq XR from the U.S. market after FDA determined there is a potential risk of cancer associated with the drug, which outweighs any benefit of weight loss. FDA approved the drug in 2012 as an add-on therapy to a reduced-calorie diet and increased physical activity to achieve weight loss among adults who were obese or overweight with a weight-related risk factor.

- **FDA to continue to provide updates on its response to COVID-19**

Tomorrow and this week, FDA is expected to continue to communicate on its work in response to the Novel Coronavirus Outbreak (COVID-19).

- **FDA to announce upcoming meeting of Blood Products Committee**

On Wednesday, FDA is expected to announce an upcoming Blood Products Advisory Committee meeting. Discussion topics will include current strategies to reduce the risk of Zika virus transmission by blood and blood components, an

update on the Transfusion Transmissible Infections Monitoring System and testing blood donations for hepatitis B surface antigen.

- **FDA to approve new drug for constipation (confidential)**

Tomorrow, FDA is expected to approve Pizensy as another treatment option for constipation.

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/11/2020 3:25:54 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** E&C Hearing Sidecar on Coronavirus  
**Location:** 2123 Rayburn House Office Building  
**Start:** 2/26/2020 4:00:00 PM  
**End:** 2/26/2020 5:30:00 PM  
**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan



---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/11/2020 3:25:54 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HOLD: AMA - E&C Hearing Sidecar on Coronavirus (POC: Karas)  
**Start:** 2/26/2020 4:00:00 PM  
**End:** 2/26/2020 5:30:00 PM  
**Show Time As:** Busy

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/11/2020 3:25:54 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** AMA - E&C Hearing Sidecar on Coronavirus (POC: Karas)  
**Start:** 2/26/2020 4:00:00 PM  
**End:** 2/26/2020 5:30:00 PM  
**Show Time As:** Busy

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/11/2020 4:14:40 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]

**Subject:** Commissioner Prep: White House Coronavirus Round Table  
**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975, (b)(6)

**Start:** 2/12/2020 5:45:00 PM  
**End:** 2/12/2020 6:30:00 PM  
**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Mark Abdo

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/11/2020 4:14:40 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]  
**Subject:** Commissioner Prep: White House Coronavirus Round Table  
**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975, (b)(6)  
**Start:** 2/12/2020 5:45:00 PM  
**End:** 2/12/2020 6:30:00 PM  
**Show Time As:** Busy  
  
**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Denise Hinton; Mair, Michael

---

**From:** Daniel Goldberg (b)(6)  
**Sent:** 2/11/2020 11:12:11 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]  
**Subject:** epiqar for Coronavirus assistance

Dr. Hahn,

I wanted to reach out and see if **epiqar** (<https://epiqar.com/>) can help your efforts with the Coronavirus- we are the only system in the world built for remote surgical help & interactive emergency surgeon support over the web browser.

**epiqar** has created the most advanced surgical video collaboration technology, allowing surgeons to consult and train remotely on a low-cost and easy-to-use online surgical collaboration platform and Cloud-archiving system built for the operating room. With the outbreak of Coronavirus, this has become more vital as surgeon mobility and access to critical surgical spaces in need of more help are severely limited, and specialists will not risk entering spreading viral hot zones.

Patient care isn't just a concern with the virus itself, but with the host of medical issues facing patients that will no longer be treated by local specialists easily, and facing caregivers: surgeon involvement from around the world is needed urgently.

Although **epiqar** is an American company, our rollout in recent months has been in France, making selected French institutions the most prepared in the world for remote video care. We obviously weren't anticipating the Coronavirus and now we're dedicated to delivering our technology to where the world needs it asap.

**epiqar's** parent company **ENGAUGE** (<https://eng.us/>) is a state-of-the-art online healthcare company for surgeon training and has served clients such as (b)(4) and many other of the world largest & smallest medical device companies. **ENGAUGE** has helped surgeons all over the world have access to secure online training that has improved their understanding of the innovations in robotics and many of the latest surgical techniques and medical devices for best patient care.

I've linked a whitepaper below with details of the system's use. Please let me know if you would like to speak further and/or need anything additional.

Thanks,

Danny

[www.epiqar.com](http://www.epiqar.com)

[epiqar | whitepaper](#)

Daniel Goldberg

CEO

ENGAUGE

[www.eng.us](http://www.eng.us)

[www.epiqar.com](http://www.epiqar.com)

*The world's first low-cost telementoring, surgeon training and instant Cloud-archiving Platform*

US 888.615.7874

EUROPE 44 2031399059

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/12/2020 7:22:55 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: OMB Questions on Coronavirus Supplemental Package

Thank you

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Tuesday, February 11, 2020 at 6:52 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: OMB Questions on Coronavirus Supplemental Package

FYI: (b)(5) The work is only beginning for some of our teams.

Sent from my iPhone

Begin forwarded message:

**From:** "Tootle, William" <William.Tootle@fda.hhs.gov>  
**Date:** February 11, 2020 at 6:31:22 PM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** "Tyler, James" <James.Tyler@fda.hhs.gov>, "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>, "Hebert, Angelique A." <Angelique.Hebert@fda.hhs.gov>  
**Subject:** RE: OMB Questions on Coronavirus Supplemental Package

I agree. (b)(5)  
(b)(5)

Bill Tootle

*Director, Office of Budget  
U.S. Food and Drug Administration  
4041 Powder Mill Road,  
Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Tuesday, February 11, 2020 6:23 PM  
**To:** Tootle, William <William.Tootle@fda.hhs.gov>  
**Cc:** Tyler, James <James.Tyler@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>  
**Subject:** RE: OMB Questions on Coronavirus Supplemental Package

Thanks Bill (b)(5)

**From:** Tootle, William <William.Tootle@fda.hhs.gov>  
**Sent:** Tuesday, February 11, 2020 6:19 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Tyler, James <James.Tyler@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>  
**Subject:** FW: OMB Questions on Coronavirus Supplemental Package

Hi Keagan,

I wanted to keep you informed of our responses to some recent questions from OMB related to our coronavirus response activities.

Let me know if you have any questions.

Bill Tootle

*Director, Office of Budget  
U.S. Food and Drug Administration  
4041 Powder Mill Road,  
Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

**From:** Tootle, William  
**Sent:** Tuesday, February 11, 2020 6:17 PM  
**To:** Trivedi, Aalap (OS/ASFR) <Aalap.Trivedi@hhs.gov>  
**Cc:** Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Cabezas, Miriam (OS) <Miriam.Cabezas@hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>  
**Subject:** RE: OMB Questions on Coronavirus Supplemental Package

Hi Aalap,

Please see our responses below.

(b)(5)

(b)(5)

Bill Tootle

*Director, Office of Budget  
U.S. Food and Drug Administration  
4041 Powder Mill Road,  
Beltsville, MD 20705*

*Phone: 301-796-4710/4579*

**From:** Trivedi, Aalap (OS/ASFR) <Aalap.Trivedi@hhs.gov>

**Sent:** Monday, February 10, 2020 4:00 PM

**To:** Tootle, William <William.Tootle@fda.hhs.gov>

**Cc:** Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Cabezas, Miriam (OS) <Miriam.Cabezas@hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>

**Subject:** OMB Questions on Coronavirus Supplemental Package

Hi Bill –

OMB had the following questions on the supplemental package. I know we've discussed some of these items already, but we wanted to make sure FDA had visibility and could respond. Please send us responses by 5pm tomorrow.

Thanks,  
Aalap

(b)(5)



**(b)(5)**

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/12/2020 12:11:52 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Woodcock, Janet  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Christensen, Lane  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Courtney, Brooke  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Kumar, Dinesh  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Laska, Susan F  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Lutter, Randall  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Patel, Paras M  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Roberts, Rosemary  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Sadove, Elizabeth  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Colin Rom  
(Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; McBride, Maren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Abernethy, Amy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Glover, Mark  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23fc3452dfd0414184cbb290047b7865-Mark.Glover]; McSeveney, Megan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]; Lenihan, Keagan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sigg, Jim  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A.  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Caliguiri, Laura  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rogers, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Tierney, Julia

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Rom, Colin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McBride, Maren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Abernethy, Amy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]

**Subject:** Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)  
**Location:** WO1/2102 or 1-877-465-7975,,, (b)(6)

**Start:** 2/13/2020 12:30:00 PM  
**End:** 2/13/2020 1:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Anderson, Erika; Abdo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Tyler, James; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Lutter, Randall; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth; Rom, Colin; Shah, Anand; Gross, Karas; Tantillo, Andrew; McBride, Maren; Klimczak, Katherine; Abernethy, Amy; Glover, Mark; McSeveney, Megan

**ADDITIONAL NOTE:** UPDATED TIME 12:30 PM – 1:30 PM.

**NOTE:** Commissioner Hahn and CoS Lenihan will be participating via telecon (downtown day); please feel free to join in-person (WO1/2102) or via telecon (1-877-465-7975, (b)(6))

Meeting Format:

Total 1 hour:

45 min briefing

15 min Commissioner questions/discussion, if needed

**OCS/OCET:** In order to accommodate an internal ethics review process, please send briefing materials to Emily Helms-Williams with cc to Frank Olivarria, Lindsay Tobias, and Janice Sheehy as soon as possible. Thank you!

---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/12/2020 12:11:52 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Woodcock, Janet  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Christensen, Lane  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Courtney, Brooke  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Kumar, Dinesh  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Laska, Susan F  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Lutter, Randall  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Patel, Paras M  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Roberts, Rosemary  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Sadove, Elizabeth  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Colin Rom  
(Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Maren McBride  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Abernethy, Amy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Glover, Mark  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=23fc3452dfd0414184cbb290047b7865-Mark.Glover]; McSeveney, Megan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Keagan Lenihan  
(Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Len]; Sigg, Jim  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angeliq A.  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angeliq.H]; Caliguiri, Laura  
(Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rogers, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Tierney, Julia  
 [/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]

**Subject:** Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

**Location:** WO1/2102 or 1-877-465-7975,, (b)(6)

**Start:** 2/13/2020 12:30:00 PM

**End:** 2/13/2020 1:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Anderson, Erika; Abdoo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Tyler, James; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Lutter, Randall; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth; Rom, Colin; Shah, Anand; Gross, Karas; Tantillo, Andrew; McBride, Maren; Klimczak, Katherine; Abernethy, Amy; Glover, Mark; McSeveney, Megan

**ADDITIONAL NOTE:** UPDATED TIME 12:30 PM – 1:30 PM.

**NOTE:** Commissioner Hahn and CoS Lenihan will be participating via telecon (downtown day); please feel free to join in-person (WO1/2102) or via telecon (1-877-465-7975 (b)(6))

Meeting Format:

Total 1 hour:

45 min briefing

15 min Commissioner questions/discussion, if needed

**OCS/OCET:** In order to accommodate an internal ethics review process, please send briefing materials to Emily Helms-Williams with cc to Frank Olivarria, Lindsay Tobias, and Janice Sheehy as soon as possible. Thank you!

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/12/2020 12:11:52 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Woodcock, Janet  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Christensen, Lane  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Courtney, Brooke  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Kumar, Dinesh  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Laska, Susan F  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Lutter, Randall  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Patel, Paras M  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Roberts, Rosemary  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Sadove, Elizabeth  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Rom, Colin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; McBride, Maren  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Abernethy, Amy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]

**Subject:** Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

**Location:** WO1/2102 or 1-877-465-7975, (b)(6)

**Start:** 2/13/2020 12:00:00 PM

**End:** 2/13/2020 1:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Abram, Anna; Anderson, Erika; Abdoo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Tyler, James; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Lutter, Randall; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth; Colin Rom (Colin.Rom@fda.hhs.gov); Shah, Anand; Gross, Karas;

Meeting Format:

Total 1 hour:

45 min briefing

15 min Commissioner questions/discussion, if needed

OCS/OCET: In order to accommodate an internal ethics review process, please send briefing materials to Emily Helms-Williams with cc to Frank Olivarria, Lindsay Tobias, and Janice Sheehy as soon as possible. Thank you!

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/12/2020 12:11:52 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Woodcock, Janet  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Christensen, Lane  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Courtney, Brooke  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Kumar, Dinesh  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Laska, Susan F  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Lutter, Randall  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Patel, Paras M  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Roberts, Rosemary  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Sadove, Elizabeth  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Colin Rom  
(Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; McBride, Maren  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Abernethy, Amy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Glover, Mark  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=23fc3452dfd0414184cbb290047b7865-Mark.Glover]; McSeveney, Megan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]; Lenihan, Keagan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sigg, Jim  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angeliq A.  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angeliq.H]; Caligui, Laura  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rogers, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Tierney, Julia  
 [/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]

**Subject:** Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

**Location:** WO1/2102 or 1-877-465-7975,, (b)(6)

**Start:** 2/13/2020 12:00:00 PM

**End:** 2/13/2020 1:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Anderson, Erika; Abdoo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Tyler, James; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Lutter, Randall; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth; Rom, Colin; Shah, Anand; Gross, Karas; Tantillo, Andrew; McBride, Maren; Klimczak, Katherine; Abernethy, Amy; Glover, Mark; McSeveney, Megan

**NOTE:** Commissioner Hahn and CoS Lenihan will be participating via telecon (downtown day); please feel free to join in-person (WO1/2102) or via telecon (1-877-465-7975,, (b)(6)

**Meeting Format:**

Total 1 hour:

45 min briefing

15 min Commissioner questions/discussion, if needed

**OCS/OCET:** In order to accommodate an internal ethics review process, please send briefing materials to Emily Helms-Williams with cc to Frank Olivarria, Lindsay Tobias, and Janice Sheehy as soon as possible. Thank you!

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/12/2020 12:11:52 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Christensen, Lane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]

**Subject:** Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

**Location:** WO1/2102 or 1-877-465-7975, (b)(6)

**Start:** 2/13/2020 12:00:00 PM

**End:** 2/13/2020 12:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Anderson, Erika; Abdoo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Tyler, James; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Lutter, Randall; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth; Rom, Colin; Shah, Anand; Gross, Karas; Tantillo, Andrew; McBride, Maren; Klimczak, Katherine; Abernethy, Amy

Meeting Format:

Total 1 hour:

45 min briefing

15 min Commissioner questions/discussion, if needed

OCS/OCET: In order to accommodate an internal ethics review process, please send briefing materials to Emily Helms-Williams with cc to Frank Olivarria, Lindsay Tobias, and Janice Sheehy as soon as possible. Thank you!



---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/12/2020 2:10:37 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]

**Subject:** Coronavirus Responsibilities

**Location:** HHS FDA Suite 729D

**Start:** 2/14/2020 5:00:00 PM

**End:** 2/14/2020 5:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Rom, Colin

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/12/2020 2:10:37 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** Coronavirus Responsibilities  
**Location:** HHS FDA Suite 729D

**Start:** 2/14/2020 4:30:00 PM  
**End:** 2/14/2020 5:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan; Anna Abram; Rom, Colin

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:15:55 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Colin Rom (Colin.Rom@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

**Subject:** Commissioner Pre-Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Location Pending: WO or HHS or 1-877-465-7975,,, (b)(6)

**Start:** 2/19/2020 1:15:00 PM

**End:** 2/19/2020 2:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Gross, Karas; Maren McBride; Abram, Anna; Shah, Anand; Colin Rom (Colin.Rom@fda.hhs.gov)

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Caccomo, Stephanie

---

**CC:** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Buhse, Lucinda  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03c54017a02447e1aea701cbe7c11aab-BUHSEL]; Van Pool, Kendall  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Attachments:** SH Conrovirus Hearing.Prep 2 Agenda\_final.docx

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,,, (b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Laura Caliguri; Janik, Heather; McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Caccomo, Stephanie

Principals only in the room please. Space is limited and each principal should use their discretion please if others from your teams should dial-in.

Agenda is attached – issue papers will be sent later.

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** Commissioner Prep: Murder Board (E&C Hearing Sidecar on Coronavirus)  
**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975 (b)(6)  
**Start:** 2/20/2020 3:30:00 PM  
**End:** 2/20/2020 5:00:00 PM  
**Show Time As:** Busy

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

---

**Required** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin,  
**Attendees:** Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet;  
Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth

Principals only in the room please. Space is limited and each principal should use their discretion please if others from your teams should dial-in.



**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus  
**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,

(b)(6)

**Start:** 2/20/2020 3:30:00 PM  
**End:** 2/20/2020 5:00:00 PM  
**Show Time As:** Busy

---

**Required** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin,  
**Attendees:** Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet;  
Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth

Principals only in the conference room please. Space is limited and each principal should use your discretion if others from your team should dial-in.

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbbeee5ffeb7f3d-Heather.Jan]; Caliguir, Laura (Laura.Caliguir@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

---

**CC:** Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Buhse, Lucinda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03c54017a02447e1aea701cbe7c11aab-BUHSEL]; Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,,, (b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Hahn, Stephen; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Caccomo, Stephanie

Principals only in the room please. Space is limited and each principal should use their discretion please if others from your teams should dial-in.

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,

(b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

---

**Required** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin,  
**Attendees:** Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet;  
Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Amin, Stacy; McWilliams, Carly; Janik, Heather;  
McSeveney, Megan; Anderson, Erika

Principals only in the room please. Space is limited and each principal should use their discretion please if others from your teams should dial-in.

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Janet Woodcock [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Jeffrey Shuren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Peter Marks [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus  
**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975,, (b)(6)

**Start:** 2/20/2020 3:30:00 PM  
**End:** 2/20/2020 5:00:00 PM  
**Show Time As:** Busy

---

**Required** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin,  
**Attendees:** Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Janet Woodcock;  
Jeffrey Shuren; Peter Marks; Cho, David S (CBER)

Agenda is forthcoming – CDs will not need to attend the entire 1.5 hour prep.



---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]

**Subject:** Commissioner Prep: Murder Board (E&C Hearing Sidecar on Coronavirus)

**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975, (b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Mark Abdo; McBride, Maren

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth

Agenda is forthcoming – CDs will not need to attend the entire 1.5 hour prep.

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975

(b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth

Agenda is forthcoming – CDs will not need to attend the entire 1.5 hour prep.

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcb9e5f5eeb7f3d-Heather.Jan]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975; (b)(6)

**Start:** 2/20/2020 3:30:00 PM

**End:** 2/20/2020 5:00:00 PM

**Show Time As:** Busy

**Required** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin,

---

**Attendees:** Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin; Carly McWilliams; Janik, Heather; McSeveney, Megan

Principals only in the room please. Space is limited and each principal should use their discretion please if others from your teams should dial-in.

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260E0F42-CHRISTINA.G]  
**Sent:** 2/12/2020 3:23:36 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]

**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus  
**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975, (b)(6)

**Start:** 2/20/2020 3:30:00 PM  
**End:** 2/20/2020 5:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Mark Abdo; Maren McBride

**From:** Hebert, Angelique A. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9AA08F3428A045F88EB3BD92C68A27CF-ANGELIQUE.H]  
**Sent:** 2/12/2020 5:22:20 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]  
**CC:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group



---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]

**Subject:** RE: nCoV Agency Executive Group meeting

Please dial into:

1-866-564-5562, (b)(6)

-----Original Appointment-----

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Sent:** Sunday, February 2, 2020 11:33 PM

**To:** Hinton, Denise; Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C

**Cc:** Schwartz, Suzanne; Tyler, James; Tantillo, Andrew; Gross, Karas

**Subject:** nCoV Agency Executive Group meeting

**When:** Wednesday, February 12, 2020 5:15 PM-5:45 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** 1-877-465-7975, code: (b)(6) or COO Conference Room (WO2/3305)

AEG meetings have been established to address policy and resource issues related to the nCoV public health emergency. This time is reserved to provide daily updates and discuss policy direction and guidance for our emergency response activities in consultation with Commissioner Hahn.

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/12/2020 8:05:59 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** WH event tomorrow  
**Attachments:** Agenda - 2.13.2020 v4.pdf

Hi Dr. Hahn-

Attached is a final agenda and below is list of members attending. We'll reply to this chain with the new TPs once they are ready. Let us know if you need anything before. Thanks!

Karas

**Confirmed Members:**

Senator James Risch  
Senator Tom Cotton  
Senator Gary Peters  
Leader Kevin McCarthy  
Whip Steve Scalise  
Rep. Greg Walden  
Rep. Kay Granger

---

**From:** Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109E347D6AC4]  
**Sent:** 2/13/2020 5:53:54 AM  
**To:** Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**Subject:** Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)  
**Location:** WO1/2102 or 1-877-465-7975,,, 15598371#  
**Start:** 2/13/2020 12:00:00 PM  
**End:** 2/13/2020 1:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Anderson, Erika; Abdoo, Mark; Sigg, Jim; Hebert, Angelique A.; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Tootle, William; Hinton, Denise; Amin, Stacy; Raza, Mark; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Schwartz, Suzanne; Solomon, Steven M; Forfa, Tracey; Mayne, Susan; Musser, Steven M; McMeekin, Judith; Rogers, Michael; Mair, Michael; Cho, David S (CBER); Tierney, Julia; Tyler, James; Woodcock, Janet; Agler, Heather L; Christensen, Lane; Courtney, Brooke; Jensen, Valerie E; Kumar, Dinesh; Laska, Susan F; Lutter, Randall; Patel, Paras M; Ricci, Linda J; Roberts, Rosemary; Ross, Bruce; Sadove, Elizabeth; Rom, Colin; Shah, Anand; Gross, Karas; Tantillo, Andrew; McBride, Maren; Klimczak, Katherine; Abernethy, Amy; Glover, Mark; McSeveney, Megan

Your meeting was found to be out of date and has been automatically updated.

---

Sent by Microsoft Exchange Server

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/13/2020 10:08:58 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Christensen, Lane [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Glover, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=23fc3452dfd0414184cbb290047b7865-Mark.Glover]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]

**Subject:** RE: Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

OK – so we will have the AEG on supply chain today from 12:30 – 1:00 PM. Apologies for any confusion - m

---

**From:** Mair, Michael

**Sent:** Thursday, February 13, 2020 10:02 AM

**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abdo, Mark

<Mark.Abdo@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>;

Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

**Subject:** RE: Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

**Importance:** High

Apologies to all – I am not communicating clearly this AM. We have another call from 12:00 – 12:30 – so we may reschedule the 12:00 – 1:00 PM AEG call on supply chain entirely or just change it to 12:30 – 1:00 PM.

Will clarify soon and again my apologies for the confusion. -m

---

**From:** Mair, Michael

**Sent:** Thursday, February 13, 2020 9:31 AM

**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Branch, Tiffany <Tiffanv.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Roberts, Rosemary <Rosemarv.Roberts@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Abernethy, Amy <Amv.Abernethy@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

**Subject:** RE: Commissioner Briefing Cont: 2019-nCoV Agency Executive Group (supply chain issues)

Hi. Apologies but we need to cancel the AEG meeting today b/c of a conflicting meeting. We will reschedule soon. Thx - michael

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/13/2020 10:12:21 AM  
**To:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]

**Subject:** Supply Chain Discussion w/CDC

**Location:** WO1/2102/ +1-210-795-0506 US Toll; +1-877-465-7975 US Toll Free; Meeting ID: (b)(6)

**Start:** 2/13/2020 12:00:00 PM

**End:** 2/13/2020 12:30:00 PM

**Show Time As:** Tentative

**Required Attendees:** 'Hahn, Stephen'; Hinton, Denise; Abram, Anna; Lenihan, Keagan; Agler, Heather L; Courtney, Brooke; Messonnier, Nancy E (CDC); McGowan, Robert K (CDC); Patel, Anita (CDC)

Hi. This meeting is to discuss supply chain efforts related to the 2019-nCoV outbreak.

**Location:** WO-Bldg 1/Room 2102

**Dial-in:** +1-210-795-0506 US Toll; +1-877-465-7975 US Toll Free;

**Meeting ID:** (b)(6)



---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/13/2020 10:12:21 AM  
**To:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [Denise.Hinton@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]; Messonnier, Nancy E (CDC) [nar5@cdc.gov]; McGowan, Robert K (CDC) [omc2@cdc.gov]; Patel, Anita (CDC) [bop1@cdc.gov]  
**CC:** Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]

**Subject:** Supply Chain Discussion w/CDC

**Location:** WO1/2102/ +1-210-795-0506 US Toll; +1-877-465-7975 US Toll Free; Meeting ID: (b)(6)

**Start:** 2/13/2020 12:00:00 PM

**End:** 2/13/2020 12:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Mair, Michael; 'Hahn, Stephen'; Hinton, Denise; Abram, Anna; Lenihan, Keagan; Agler, Heather L; Courtney, Brooke; Messonnier, Nancy E (CDC); McGowan, Robert K (CDC); Patel, Anita (CDC)

Hi. This meeting is to discuss supply chain efforts related to the 2019-nCoV outbreak.

**Location:** WO-Bldg 1/Room 2102

**Dial-in:** +1-210-795-0506 US Toll; +1-877-465-7975 US Toll Free;

**Meeting ID:** (b)(6)

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/13/2020 10:12:21 AM  
**To:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [Denise.Hinton@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]; Messonnier, Nancy E (CDC) [nar5@cdc.gov]; McGowan, Robert K (CDC) [omc2@cdc.gov]; Patel, Anita (CDC) [bop1@cdc.gov]

**Subject:** Supply Chain Discussion w/CDC

**Location:** WO1/2102/ +1-210-795-0506 US Toll; +1-877-465-7975 US Toll Free; Meeting ID: (b)(6)

**Start:** 2/13/2020 12:00:00 PM

**End:** 2/13/2020 12:30:00 PM

**Show Time As:** Busy

**Required Attendees:** 'Hahn, Stephen'; Hinton, Denise; Abram, Anna; Lenihan, Keagan; Agler, Heather L; Courtney, Brooke; Messonnier, Nancy E (CDC); McGowan, Robert K (CDC); Patel, Anita (CDC)

Hi. This meeting is to discuss supply chain efforts related to the 2019-nCoV outbreak.

**Location:** WO-Bldg 1/Room 2102

**Dial-in:** +1-210-795-0506 US Toll; +1-877-465-7975 US Toll Free;

**Meeting ID:** (b)(6)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/13/2020 11:50:36 AM  
**To:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FW: Final material for roundtable  
**Attachments:** Agenda - 2.13.2020 v4.pdf; Hahn-WH Coronavirus Roundtable\_OL and IMG.docx; Updated TPs.rtf  
**Importance:** High

Could you print for me?

Thanks

S

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>  
**Date:** Thursday, February 13, 2020 at 7:50 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>, Karas Gross <Karas.Gross@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, Denise Hinton <Denise.Hinton@fda.hhs.gov>, "Mair, Michael" <Michael.Mair@fda.hhs.gov>  
**Subject:** Final material for roundtable

So you have everything in one email...

First attachment: Final agenda and list of members attending below.

Second attachment: Long TPs (reviewed last night)

Third attachment: Addendum to TPs

**Confirmed Members:**

Senator James Risch  
Senator Tom Cotton  
Senator Gary Peters  
Leader Kevin McCarthy  
Whip Steve Scalise  
Rep. Greg Walden  
Rep. Kay Granger

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/13/2020 12:37:45 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: Murphy/Rubio letter

Thank you. The team is feeling pulled in many directions and wants to make sure we have alignment on your preference for triaging the multiple and competing requests. Thanks!

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Thursday, February 13, 2020 12:35 PM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: Murphy/Rubio letter

That is reasonable.  
Steve

---

**From:** Anna Abram <Anna.Abram@fda.hhs.gov>  
**Date:** Thursday, February 13, 2020 at 12:03 PM  
**To:** Anand Shah <Anand.Shah@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Murphy/Rubio letter

Thanks, Anand. The draft response is working its way through clearance.

Collapsing this down to a smaller group. I would suggest that we touch base in our Friday huddle (b)(5)

(b)(5)

Thanks!

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Thursday, February 13, 2020 10:50 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>  
**Subject:** RE: Murphy/Rubio letter

Hi Denise / Karas-

When do you anticipate a draft response for the Commissioner to review?

Thank you

Anand

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Sent:** Sunday, February 9, 2020 1:39 PM

**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>

**Subject:** RE: Murphy/Rubio letter

Thx Denise

---

**From:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>

**Date:** February 9, 2020 at 1:11:26 PM EST

**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>

**Subject:** RE: Murphy/Rubio letter

Thanks - all Centers/ORAs are represented on IMG. We'll work together to provide an informative response as we continue to assess our opportunities and mitigate risks.

Thanks,

Denise

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>

**Sent:** Sunday, February 9, 2020 10:14 AM

**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>

**Subject:** Re: Murphy/Rubio letter

And after skimming letter

(b)(5)

(b)(5)

Thanks!

Off line for next hour and then back online for today.

---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>

**Date:** February 9, 2020 at 10:11:30 AM EST

**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Hinton, Denise

<Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

**Subject:** Re: Murphy/Rubio letter

Thanks, all, for working with and through IMG so we are fully in sync.

Plus Denise and Michael.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Date:** February 9, 2020 at 9:50:25 AM EST

**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** Re: Murphy/Rubio letter

Thanks

---

**From:** Karas Gross <Karas.Gross@fda.hhs.gov>

**Date:** Sunday, February 9, 2020 at 9:48 AM

**To:** Stephen Hahn <SH1@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Maren McBride <Maren.McBride@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>

**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>

**Subject:** RE: Murphy/Rubio letter

Our teams are working the letter and response through the IMG now and aim to meet the 2/18 deadline in the letter. Happy to discuss further.

Karas

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>

**Sent:** Sunday, February 9, 2020 9:37 AM

**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** Murphy/Rubio letter

Good morning Karas and Maren,

I'd like to be able to respond to this query fairly quickly given the rapidly evolving situation. Let's discuss. Anand, would you discuss some of the specifics with CDER and CBER?

Thanks.

Steve

<https://www.murphy.senate.gov/newsroom/press-releases/murphy-rubio-urge-fda-to-ensure-the-safety-and-supply-of-pharmaceuticals-food-and-medical-supplies-amid-growing-coronavirus-epidemic>

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/13/2020 12:38:11 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: Snap shot of supply info  
**Attachments:** CDC Supply Update. 02132020\_Patel.pdf

Nancy's email is in the chain below

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Sent:** Thursday, February 13, 2020 12:33 PM  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Subject:** Fwd: Snap shot of supply info

For internal use. The slides Dr. Messonnier mentioned during our call.

---

**From:** Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>  
**Date:** February 13, 2020 at 11:24:24 AM EST  
**To:** Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>  
**Cc:** Jemigan, Daniel B (CDC) <dbj0@cdc.gov>, Messonnier, Nancy E (CDC) <nar5@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Subject:** Snap shot of supply info

Hi Laura,

Please see attached. Truncated the distro from what was on the SOC email. Also, do you know if ASPR will be sharing materials that will be used for tomorrow?

+ Brooke

Thanks,  
Anita

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/13/2020 4:35:45 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]  
**Subject:** Ready for your review: outbreak statement  
**Attachments:** Draft Statement for SH REVIEW .docx  
**Importance:** High

This has been cleared through FDA and is ready for your review. Please let us know if you have any edits. Standing by and thank you.



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/13/2020 5:20:48 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FW: 13 Feb FDA SITREP for review  
**Attachments:** 16\_2019-nCoV Outbreak\_FDA SITREP\_13 February 2020.docx

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/13/2020 5:29:48 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: Ready for your review: outbreak statement  
**Attachments:** Draft Statement for SH REVIEW [1]-SMH comments.docx

Thanks much. My comments.  
Steve

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>  
**Date:** Thursday, February 13, 2020 at 4:35 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, Laura Caliguiri <Laura.Caliguiri@fda.hhs.gov>, "McSeveney, Megan" <Megan.McSeveney@fda.hhs.gov>  
**Subject:** Ready for your review: outbreak statement

This has been cleared through FDA and is ready for your review. Please let us know if you have any edits. Standing by and thank you.

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/14/2020 7:01:15 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]  
**CC:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbeye5ffeeb7f3d-Heather.Jan]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]  
**Subject:** Fwd: Coronavirus Could Infect Two-Thirds of Globe, Research Shows

---

**From:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Date:** February 13, 2020 at 11:56:16 PM EST  
**To:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>  
**Subject:** Coronavirus Could Infect Two-Thirds of Globe, Research Shows

<https://apple.news/Ax-sxlq2BQVSyV66XfsO-hA>

---

**From:** Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109E347D6AC4]  
**Sent:** 2/14/2020 10:18:37 AM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]  
**Subject:** Coronavirus Responsibilities  
**Location:** HHS FDA Suite 729D  
**Start:** 2/14/2020 5:00:00 PM  
**End:** 2/14/2020 5:30:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Rom, Colin

Your meeting was found to be out of date and has been automatically updated.

**Updated meeting details:**

The meeting was canceled.

---

Sent by Microsoft Exchange Server

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/14/2020 2:45:58 PM  
**To:** Kahn, Alan (HSGAC) [Alan\_Kahn@hsgac.senate.gov]  
**CC:** Weinberg, David (HSGAC) [David\_Weinberg@hsgac.senate.gov]; Schram, Zachary (HSGAC) [zachary\_schram@hsgac.senate.gov]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]  
**Subject:** RE: Meeting with Senator Peters on Covid-19 response efforts

Hi Alan-

Thanks for reaching out. Moving the Commissioner and Janice to Bcc. I know he very much enjoyed his conversation with Senator Peters and found it very helpful and constructive. I've added Andy from my team, so we can find a time to chat with you to find out how we can be most helpful. Thank you again!

Karas

---

**From:** Kahn, Alan (HSGAC) <Alan\_Kahn@hsgac.senate.gov>  
**Sent:** Friday, February 14, 2020 12:55 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Weinberg, David (HSGAC) <David\_Weinberg@hsgac.senate.gov>; Schram, Zachary (HSGAC) <zachary\_schram@hsgac.senate.gov>  
**Subject:** Meeting with Senator Peters on Covid-19 response efforts

Dear Commissioner Hahn,

Senator Peters asked that our staff contact your office following yesterday's White House meeting on Covid-19 response efforts and your offer to continue discussions among staff with respect to supply chain, foreign inspections, and related concerns.

I wanted to introduce myself and offer to coordinate timing for a meeting with your staff. I spoke briefly just now with your assistant and believe I have included the appropriate legislative affairs contact in this email, but am happy to follow-up however your office prefers. Thank you again for your offer to work with Senator Peters on this issue.

Sincerely,  
Alan Kahn

Alan Kahn  
Senior Investigative Counsel  
U.S. Senate Committee on Homeland Security & Governmental Affairs  
Senator Gary C. Peters, Ranking Member

---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/14/2020 3:50:52 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** RE: Tweet thread approval  
**Attachments:** Social Media - nCoV - 2.14.20 AA.docx

Please see correction on the (b)(5)

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Friday, February 14, 2020 3:38 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** Tweet thread approval

Are you all ok with this tweet thread going? OMA is ready to post

---

**From:** Janik, Heather <Heather.Janik@fda.hhs.gov>  
**Date:** February 14, 2020 at 2:49:39 PM EST  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** Social Media

Update in a word doc if you'd like to print for SH. Thanks!

**Heather Janik**  
*Assistant Commissioner, Office of Media Affairs*

Office of External Affairs  
U.S. Food and Drug Administration  
Office: (240) 402-3789 Cell: (b)(6)  
heather.janik@fda.hhs.gov



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/14/2020 7:39:07 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]  
**Subject:** Follow Up on HOLD: AMA daily Coronavirus Update

It was determined at this morning's calendar meeting that we would decide day before/day of if SH would participate in Monday's AMA Coronavirus Update. As of this evening, the meeting is canceled. Will provide an update if it comes back onto the calendar for Monday.

Thank you, have a great weekend!  
Frank

-----Original Appointment-----

**From:** Secretary Scheduler (OS/IOS) <Secretary.Scheduler@hhs.gov>  
**Sent:** Friday, February 14, 2020 5:15 PM  
**To:** Sheehy, Janice; Olivarria, Frank; Goldie, Christina  
**Subject:** Canceled: HOLD: AMA daily Coronavirus Update  
**When:** Monday, February 17, 2020 3:15 PM-3:45 PM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** 610-F  
**Importance:** High



---

**From:** Microsoft Outlook [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MICROSOFTEXCHANGE329E71EC88AE4615BBC36AB6CE41109E347D6AC4]  
**Sent:** 2/15/2020 11:32:29 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Commissioner Prep: E&C Hearing Sidecar on Coronavirus  
**Location:** Commissioner's Suite (WO1/2217) or 1-877-465-7975,, (b)(6)  
**Start:** 2/20/2020 3:30:00 PM  
**End:** 2/20/2020 5:00:00 PM  
**Show Time As:** Tentative

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA)

Your meeting was found to be out of date and has been automatically updated.

---

Sent by Microsoft Exchange Server

**From:** hellen wang (b)(6)  
**Sent:** 2/16/2020 2:04:51 AM  
**To:** Birnbaum, Linda S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8300da382e694867abf2cba1e3cae160-HHS-birnbaum]; Woychik, Rick P (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e542feb12459aa7dd922d0508b6b2-HHS-rick.wo]; Miller, Mark F (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10e321b3056d4103afd67b5fcf7106d7-HHS-mark.mi]; Jacobson, Mary E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e18e7b4941e0401fb0ba879014e790b1-HHS-mary.ja]; Evans, Sharon L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec711a52d2ef4307a506f180b4e9e1bb-HHS-EvansS-]; laura.watson (b)(6)  
Eason, Allison A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b31686b7ccb44971affb3c7aef1420bd-HHS-allison]; Hudd, Kay A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=667188a69ef04b0aaef7bd7f3d3a3cdd-HHS-kay.hud]; Smith, Spencer S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=070bca6e229f41d19798aa7afc40b544-HHS-spencer]; 2020 (b)(6)  
nhlbiinfo (b)(6); niaic (b)(6); niaaaweb-r (b)(6); ocpostoffice (b)(6)  
NIAMSinfo (b)(6); info (b)(6); NICHDIInformationResourceCenter (b)(6)  
nidcdinfo (b)(6); nidcrinfo (b)(6); healthinfo (b)(6); webcenter (b)(6)  
info (b)(6); nimhinfo (b)(6); NIMHInfo (b)(6); info (b)(6)  
csrwebmaster (b)(6); ficinfo (b)(6); info (b)(6); info (b)(6) Arnone, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3249bca5836c4d1bb9d051eee85026b2-James.Arnon]; Hodges, Garland  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f986d2f719b439885be44a0c306f763-Garland.Hod]; Turco, Dean  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8a6b3ed984b4b60b0be48f9ed6d2f4d-Dean.Turco];  
 george.graber@fda.gov; Burkholder, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d5fda60a4814bd290d84bd28a2a9292-BBURKHOL]; james.bona@fda.gov;  
 stephanie.magill@fda.gov; linda.wilmot@fda.gov; Beaulieu, Andrew J\* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99772588da104f83a39ab2742c962f81-ABEAULIE];  
 mary.brady@fda.gov; mark.schmall@fda.gov; linda.webb@fda.gov; david.newkirk@fda.gov;  
 joan.gotthardt@fda.gov; Strambler, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9e7f400f70b4e3eaa22acf93adb82b8-KStrambler]; Milone, Joseph  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7fa181e8bdf495e8a2ad3d9c4669408-JXM2]; Jansen, Darren  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db3fd2f194e74e2bb89521b803e95f1a-Darren.Jans]; Smith, Michelle A  
 (CFSSAN) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccd9c9b7353949b1b78b01b57988b7b1-MAS8]; Anderson, Amy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=445ffa79c5f847c582d792b730829f34-Amy.Anderso]; McMillian, Carolyn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dfd4045d00e4b18a0f789f79b0cd954-Carolyn.McM]; mary.hitch@fda.gov;  
 daniel.benjamin@fda.gov; cynthia.polit@fda.gov; john.harshman@fda.gov; marc.hess@fda.gov; zoe.gill@fda.gov;  
 Bataller, Neal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2458a8e78711449395cdc90423c00a6c-NBATALLE]; Dunham, Bernadette  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c09660765a164cb9988e6fe505b8286c-Bernadette.]; pam.scott@fda.gov;  
 Benz, Daniel A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de24adc8414e4ffa8926921c317a44f8-DBENZ]; phillip.osborne@fda.gov;  
 Krantz, Zoe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3781bbde81cf486d9f2447ff29ddedb3-ZKrantz]; susan.hight@fda.gov;  
 Cheng, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f44e11612254a8296baf31efef62e4f-John.Cheng];

marcia.madriral@fda.gov; debra.lewis@fda.gov; Dubbin, Eric S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ca35a5c26754a94936ccc2ba454e994-EDUBBIN]; brenda.boateng@fda.gov; steve.toigo@fda.gov; marjorie.jenkins@fda.gov; robert.ottaviano@fda.gov; Wooten, Toni V [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b63a745ca45401dad3dac4ef05ce7dd-TWOOTEN]; Hungerford, James M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=200f87222ae04feb9299fbd2497ea375-James.Hunge]; linda.grassie@fda.gov; jjohannessen@fda.gov; Anderson, Chanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b670a6f99ca4f1b8fd22a826feb4a25-Chanda.Ande]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; edmond.baratta@fda.gov; mary.poos@fda.gov; keith.webber@fda.gov; Clarke, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09ecd711173a4e3db920ef6786f5bfd3-ACLARKE]; Buckler, Wendy S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35f9c40840524cac8ff494ddd5ba7b64-WBUCKLER]; melanie.berson@fda.gov; lonnie.luther@fda.gov; christine.rynkiewicz@fda.gov; burt.pritchett@fda.gov; michael.owen@fda.gov; Quick Questions [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28d5d6a0a74a486e812e6519ee632e66-quickquesti]; drugs@fda.gov; BadAd [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8a8162002ed4a62b571fc8f798de298-BadAd]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; FDA FURLS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f2f79b4501e4502a5e6017630ad139b-FDAFURLS]; Industry.Biologics [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77a373c811df4854971fd642ebfdb54b-Industry.Bi]; OC Combination Products [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dec648ce1a84825910b2937ab184359-combination]; CFSAN-Industry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15041aa2290245fba3c546faa0dd7b80-CFOCO3]; CFSAN-Consumer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2e241981934400f8bd471c0b7cc790f-CFOCO2]; Dhingra, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4c59af3c1b94561b71ef1df7bf30d45-Amber.Dhing]

**Subject:** Wuhan Virus , Biotech weapon due to inside China fight of power ? Wuhan Virology Institute had closed virus since 2015 !

Dear All

China president Xi Jinping just sent No1 army anti biochemistry weapon professional lady ( who also led SARS before ), Wei Liu to go to Wuhan to take charge of Wuhan Virology Institute, Chinese Academy of Science. <https://baike.baidu.com/item/%E9%99%88%E8%96%87/13347752>

What does it mean ? Please see a recent Wuhan Virology research on Wuhan Virus , this report was sent on 1/20 ( same day that Xi Jinping confirmed for Wuhan virus, accepted on 1/29 and published on 2/3 , you could see dates in the article on Nature)

A pneumonia outbreak associated with a new coronavirus of probable bat origin  
[https://www.nature.com/articles/s41586-020-2012-7?error=cookies\\_not\\_supported&code=0233cd6f-0bd6-480d-b7b3-9c8cf23bf072](https://www.nature.com/articles/s41586-020-2012-7?error=cookies_not_supported&code=0233cd6f-0bd6-480d-b7b3-9c8cf23bf072)

**However, the same author Shi ZL at Wuhan Virology Institute had a familiar result in 2015 !**

A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence.  
<https://www.ncbi.nlm.nih.gov/pubmed/26552008>

Compare of this two article , this lady Shi ZL has been study on Bat virus for many years, and both her two article all shows the virus got into human through **ACE2 !!! How much chance for a virus in bat that could automatically mutated with exactly same change as a virus from human lab ?**

on 2015 Declan Butler already question this research : Engineered bat virus stirs debate over risky research  
<https://www.nature.com/news/engineered-bat-virus-stirs-debate-over-risky-research-1.18787>

The current director is a a very young lady called Yantie Wang, she and her husband links to Formal President Jiang Zemin ( whose elder son used to control Chinese Academy especially in Shanghai and wuhan) Any Chinese could tell based on her resume and age , she definitely is not quality to be director of Wuhan Virology Institute, Chinese Academy of Science if there is no any backup from powerful person ! Right after virus started, Shanghai institute of pharmacy and wuhan virology institute comes out a 双黄连 medicine ( just a general one not really target to this time virus) , indicate wuhan and shanghai does have very close relationship !

<https://www.secretchina.com/news/gb/2020/02/08/922350.html>

More interesting, Beijing capital university director Raoyi reported on Nov 2019 Shanghai pharmacy institute director , together with one professor Hongliang li in wuhan university medical research ( where Yantie Wang husband Shu hongbin [https://en.wikipedia.org/wiki/Shu\\_Hongbing](https://en.wikipedia.org/wiki/Shu_Hongbing) in Charge) making fake scientific research reports, not sure whether those are related though. We also can see a clear relationship here of shanghai and wuhan and this Hongliang li also responsible for animals ( he used monkey for his research) .

[https://www.guancha.cn/politics/2019\\_11\\_29\\_526848.shtml](https://www.guancha.cn/politics/2019_11_29_526848.shtml)

<https://wenhui.whb.cn/third/baidu/201810/29/220757.html?sdkver=1caf3c13&clientprefetch=1>

Please note as today if use biotech and combine research together , it is possible that bio-weapon could make a virus attack to multiple organs at the same time !

Please help fully investigate Wuhan virus right away !

Sincerely

Hong Wang

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/17/2020 7:50:09 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Tentative: AMA daily Coronavirus Update  
**Start:** 2/1/2020 3:30:00 PM  
**End:** 2/1/2020 4:00:00 PM  
  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/17/2020 7:50:11 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Tentative: AMA daily Coronavirus Updates  
**Location:** 610-F  
**Start:** 2/2/2020 3:30:00 PM  
**End:** 2/2/2020 4:00:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/18/2020 10:37:29 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: nCoV Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: [REDACTED] (b)(6)  
**Start:** 2/17/2020 5:15:00 PM  
**End:** 2/17/2020 5:45:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/18/2020 10:46:28 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: CDER Comms on COVID-19

Thanks

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Monday, February 17, 2020 at 11:28 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: CDER Comms on COVID-19

Looks like CDER is on it now.

Sent from my iPhone

Begin forwarded message:

**From:** "Rawlings, Kimberly" <Kimberly.Rawlings@fda.hhs.gov>  
**Date:** February 16, 2020 at 8:24:26 PM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** CDER Comms on COVID-19

Hi Keagan,

Doug Throckmorton meet with me and members of the CDER IMG about making adjustments to CDER communications internally regarding the center's COVID-19 activity. In addition to making the CDER sitrep reports more robust, CDER is in the process of drafting a foundational summary to share with you as soon as possible. The summary will provide an overview the work on COVID-2019 on drug development and drug shortages. Let me know if the summary will be helpful.

Kim

**Kimberly A. Rawlings**  
Deputy Director  
Office of Communications, CDER

U.S. Food and Drug Administration  
Tel: 301-796-3818; Mobile: (b)(6)  
Kimberly.rawlings@fda.hhs.gov





---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/18/2020 12:10:37 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: Supply chain updates: N95s

**Importance:** High

FYI – this remains dynamic, but the readout below from OCET is timely on the N95 front...

Internal confidential

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Sent:** Tuesday, February 18, 2020 10:23 AM  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>  
**Subject:** Supply chain updates: N95s  
**Importance:** High

Good morning,

We can provide more information during this afternoon’s AEG meeting, but wanted to share some supply chain updates just in case the issues are raised in any high level meetings or briefings today. At this time, below is just intended for internal situational awareness purposes and we still haven’t heard of widespread shortages or issues.

(b)(5)

We want to reiterate that the above information provides just a snapshot at this time, some of the information is anecdotal, and we haven’t yet heard of widespread shortages or issues at health care facilities, but we want to be prepared in the coming weeks for the possibility of additional health care facilities and states noting similar supply

concerns as above, especially with N95s. We continue to coordinate very closely with CDC, which is working on additional outreach. And CDRH of course continues to lead with its excellent efforts and outreach with manufacturers. So with lots of moving parts, multiple agencies with different roles, and an evolving situation, the messaging on this will need to be very carefully balanced and closely coordinated/aligned with CDC, NIOSH, ASPR, etc. (we've already connected CDC's supply chain comms lead with April).

We'll plan to provide additional information during this afternoon's AEG meeting, including potential IA options being discussed to help with mitigating potential spot shortages (e.g., EUA coverage for non-surgical N95s, use of "expired" N95s and surgical masks held in state and local stockpiles, etc.) and what some of our federal partners are doing (e.g., ASPR/Hospital Preparedness Program, CDC, SNS, etc.) and how we should best coordinate with them on N95 response actions and messaging. But, again, we wanted to give you an update this morning just in case any of these issues are raised with leadership today.

Thanks,  
Brooke

Brooke Courtney, JD, MPH  
Senior Regulatory Counsel  
Office of Counterterrorism and Emerging Threats (OCET)  
Office of the Commissioner  
U.S. Food and Drug Administration  
301-796-0376 (office) | (b)(6) | cell)  
brooke.courtney@fda.hhs.gov

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/18/2020 12:31:40 PM  
**To:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**CC:** Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Re: Scanned: COVID-19 Containment & Mitigation Planning PowerPoint

Thanks, Frank

---

**From:** Frank Olivarria <Frank.Olivarria@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 12:25 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** "Copeland, Jakea" <Jakea.Copeland@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Subject:** Scanned: COVID-19 Containment & Mitigation Planning PowerPoint

Dr. Hahn,

The document (slide deck) you wanted added to your digital materials has been added to the folder for 02.12 (the date the PowerPoint is dated). Here is a link to the scanned document: [1745-SCANNED HANDOUT-COVID-19 Containment + Mitigation Planning](#) <sup>NEW</sup>. The entire day's folder where this digital copy is stored, is here: [02.12](#).

Let us know if you have any issues accessing this scanned document.

Thank you,  
Frank

**Frank A. Olivarria**  
Management and Program Analyst  
Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel 240-402-9882  
Frank.Olivarria@fda.hhs.gov



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/18/2020 6:39:36 PM  
**To:** Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]  
**CC:** Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]  
**Subject:** Re: TWEETS for REVIEW: Coronavirus (TUES)

Approved  
Thx Brad  
Steve

---

**From:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Date:** February 18, 2020 at 6:00:33 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Stark, Angela <Angela.Stark@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>  
**Subject:** TWEETS for REVIEW: Coronavirus (TUES)

Good evening. Here are some tweets on COVID for your review. Thanks! --Brad

===

### Coronavirus (TUES)

1. Unfortunately, during emergency situations, fraudulent products claiming to prevent, treat or cure diseases almost always appear for sale. We monitor and take appropriate action against false #COVID19 product claims to protect consumers.
2. There are no FDA-approved vaccines to prevent COVID-19 or novel #coronavirus. We have established a cross-agency task force dedicated to closely monitoring for fraudulent products and false product claims related to #COVID19.
3. There are no FDA-approved drugs to treat COVID-19 or other coronaviruses. The FDA is committed to taking action to prevent unscrupulous actors from marketing unlawful products related to the #coronavirus outbreak. #COVID19

4. Be cautious of misinformation circulating online and on social media about novel coronavirus. Exaggerated claims or anecdotal evidence aren't substitutes for talking with your healthcare provider. #COVID19Fraud

**Brad Kimberly**

*Director, Social Media*

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-1002 | Cell: (b)(6)

brad.kimberly@fda.hhs.gov



---

**From:** Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]  
**Sent:** 2/18/2020 7:28:17 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Feb 18 COVID SIT REP  
**Attachments:** 18\_2019-nCoV Outbreak\_FDA SITREP\_18 February 2020.docx  
**Importance:** High

Dr. Hahn, today's sit rep is attached. Thanks.

Internal confidential

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/19/2020 6:57:31 AM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Re: Today's USA Today

Thanks

---

**From:** "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Date:** Tuesday, February 18, 2020 at 10:58 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: Today's USA Today

Flagging

---

**From:** Janik, Heather <Heather.Janik@fda.hhs.gov>  
**Date:** February 18, 2020 at 3:30:26 PM EST  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Subject:** Today's USA Today

Just a nice thing to flag or add to evening packet if possible. Thank you!

<https://www.usatoday.com/story/news/health/2020/02/18/coronavirus-halts-fda-inspections-china-might-disrupt-drug-supply/4788157002/>

# FDA: China's coronavirus might disrupt 'critical medical products' including drugs and devices

Ken Alltucker Jayne O'Donnell

USA TODAY

The Food and Drug Administration has pulled inspectors from China amid the rapidly-spreading coronavirus and has warned Americans might face shortages of “critical medical products” if the outbreak persists.

The federal agency halted inspections of drug and device factories due to the State Department warning against travel to China. The FDA has faced Congressional scrutiny for its oversight of overseas factories following high-profile recalls of blood pressure-lowering medications and reports revealing fewer overseas inspections in recent years.

Although the coronavirus outbreak seems to put the federal agency behind schedule on routine safety and quality checks of drug and device factories, Commissioner Stephen Hahn said the agency can still monitor China-made products through testing, records requests and "import bans" that forbid products from entering the U.S.



“The robust and multi-layered compliance process at the FDA is helping to protect American patients and consumers even though we are not able to conduct inspections in China at this time,” Hahn said in a statement.

The FDA’s database of inspections, current as of Feb. 7, shows the agency has not listed any inspections of a Chinese factory since last December. Inspections in China typically slow down in January around the time of Chinese New Year, but the absence of on-site safety and quality checks will now extend into March.

The FDA inspects when an overseas factory seeks approval to supply drugs or drug ingredients for the American market. Factories are also subject to periodic “surveillance” inspections to gauge whether they are meeting quality standards. When the agency



becomes aware of a possible safety problem with a drug or manufacturing process the FDA conducts "for cause" inspections.

Hahn said all inspections scheduled for February were postponed or the agency used "other information to inform decisions allowing the products to enter our U.S. market." He said 90% of those inspections were routine surveillance. The agency also delayed this month's scheduled for-cause inspections after analyzing information for each factory in question. Most surveillance inspections scheduled for March at drug and medical device factories already have been postponed, he said. The agency did not address inspections in January.

"We will continue to closely monitor the situation in China so that as the situation improves, we will be prepared to resume routine inspections," he said.

The FDA has faced questions from lawmakers about how the coronavirus outbreak has affected the agency's oversight of drug and device factories. And last December, before the outbreak was known, a Government Accountability Office report revealed the number of inspections at overseas factories dropped 10% from 2016 to 2018 and found "persistent challenges" such as not hiring and retaining enough inspectors.

Michael Carome is director of Public Citizen's health research group and an expert on drug safety and FDA oversight.

"The fact that the FDA has suspended inspections is worrisome," Carome said. "We start from a baseline position of they are not doing enough inspections in China, where the active ingredients for a lot of our drugs are made. Any further delay or suspension in their inspections makes the problem worse."

Carome said a short suspension probably won't make a huge difference. However, if the outbreak delays inspections for several weeks or months "that's going to impact drug safety," he said.

Another potential problem: The U.S. might need to navigate drug or medical product shortages if the coronavirus outbreak continues to snarl production in China, a pivotal supplier for American consumers, doctors and hospitals.

Hahn said the agency is "keenly aware" the coronavirus outbreak "will likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the U.S."

The agency has reached out to manufacturers and shifted resources to identify potential medical product shortages. He said the agency is tracking reports of increased orders of medical devices such as masks, gloves, respirators and surgical gowns.

Howard Sklamberg, a former FDA deputy commissioner overseeing foreign inspections during the Obama administration, said the agency tries to take action to avert drug and medical device shortages. Some strategies might include finding other suppliers, possibly in another country, or accelerating approval of a drug from another manufacturer awaiting FDA review.

Some drug or device supply disruptions can be predicted, such as when a company alerts the FDA of plans to discontinue a drug or suspend production due to a manufacturing problem. Other times, the change can be sudden. In 2017, Hurricane Maria slammed Puerto Rico and shut down production at drug factories that made critical supplies such as saline solution.

“This type of thing happens more frequently than one might think,” Sklamberg said of drug shortages. “It happens when there is a weather problem. Oil spills. Or there could be a situation like a civil war,” which can disrupt production or make it impossible for inspectors to access a factory.

Even if inspectors are shut out of routine surveillance or “for-cause” checks, the FDA has other options to protect consumers from receiving tainted products. The agency can halt overseas shipments of problem drugs, devices or food through “import alerts” coordinated with customs and border enforcement officials.

Whether the coronavirus disrupts drug supplies “largely depends on how long the emergency continues and how broad the geographic area is,” said Sklamberg, now a partner in the law firm Akin Gump.

“The supply chain and the level of inventory in the US already varies a lot by drug. It’s hard to make an overall statement, other than it depends on how long this goes on.”

Tom Cosgrove, a former director of FDA’s office of manufacturing quality, said the FDA’s inspection system is very flexible.

“The issue is, how will the FDA inspection regime fare if they can’t access China?” said Cosgrove, now a partner in the law firm Covington & Burling.

If the quarantine succeeds and inspections resume “within a couple of months, I don’t think there will be a major impact on the FDA. But if it’s more than a couple months, the FDA could fall behind on its inspection program and it would take a long time to catch up.”

**Heather Janik**

*Assistant Commissioner, Office of Media Affairs*

Office of External Affairs

U.S. Food and Drug Administration

Office (240) 402-3789 Cell (b)(6)

heather.janik@fda.hhs.gov



---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/19/2020 11:19:47 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HOLD: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus  
**Attachments:** FW: Hearing Notice HELP Committee 3.3.20  
**Location:** 430 Dirksen Senate Office Building  
**Start:** 3/3/2020 10:00:00 AM  
**End:** 3/3/2020 2:30:00 PM  
**Show Time As:** Busy

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/19/2020 11:19:47 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus  
**Attachments:** FW: Hearing Notice HELP Committee 3.3.20  
**Location:** 430 Dirksen Senate Office Building  
**Start:** 3/3/2020 10:00:00 AM  
**End:** 3/3/2020 12:00:00 PM  
**Show Time As:** Busy

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/19/2020 11:19:47 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Subject:** HOLD: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus  
**Attachments:** FW: Hearing Notice HELP Committee 3.3.20  
**Location:** 430 Dirksen Senate Office Building  
**Start:** 3/3/2020 10:00:00 AM  
**End:** 3/3/2020 1:00:00 PM  
**Show Time As:** Busy

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/19/2020 4:59:26 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: Draft Note to China Office Colleagues - Internal, Confidential

Thanks—sending now.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Wednesday, February 19, 2020 4:57 PM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Draft Note to China Office Colleagues - Internal, Confidential

Hahn cleared!

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Sent:** Wednesday, February 19, 2020 4:30 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Draft Note to China Office Colleagues - Internal, Confidential

Dr. Hahn, have you had a chance to review the note prepared for the China Office employees? Once you clear, I'll send out on your behalf.

---

**From:** Abram, Anna  
**Sent:** Wednesday, February 19, 2020 12:23 PM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Draft Note to China Office Colleagues - Internal, Confidential

In follow up to our thread from last week, below please find a draft that OGPS pulled together and has run by Jim Sigg and OCC for clearance. We are compiling the list to whom the note would be sent and I also plan on sending a note of support this week. I suspect you may want to further revise to put in your voice, such as the language around your previous travel to China. Let us know if you need anything further from OPLIA/OGPS on this and thank you for the follow up to our colleagues, I know they will appreciate it.

+ Colin

Commissioner Hahn / Note to China Office

Dear Colleagues,

I want you to know that since the outbreak of COVID-19, all of you have been on my mind, and on the minds of many FDA leaders. We are all glad that you're back safely. I am certain the past few weeks have been

disruptive and hope that you and your families are settling in. Please know that the Agency is here to support you

Deputy Commissioner Abram and Mark Abdo have briefed me on the work of the Office of Global Policy and Strategy and the importance of our overseas presence. I understand the importance of our foreign offices and am glad we have staff like you abroad and admire the work you do to keep Americans safe.

On a personal note, I am no stranger to China. In fact, in my previous jobs, I've spent quite a bit of time there. I know how crowded its cities are and I must say seeing media pictures of deserted streets in Beijing was truly eerie.

Coronavirus reminds us that a global organization like FDA faces many challenges. We will make it through this one stronger and more resilient.

Thank you for your dedication to FDA's public health mission. Your spirit and strength show all of FDA – and the American people – what public serve truly means.

Commissioner Hahn



---

**From:** Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]  
**Sent:** 2/19/2020 6:47:00 PM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddb3e55f5eb7f3d-Heather.Jan]; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]  
**Subject:** Filming: Commissioner's Corner - Coronavirus  
**Location:** HHS Studio  
**Start:** 2/21/2020 2:30:00 PM  
**End:** 2/21/2020 2:45:00 PM  
**Show Time As:** Busy

**Required Attendees:** Janik, Heather; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/20/2020 8:35:35 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/20/2020 3:30:00 PM  
**End:** 2/20/2020 4:00:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/20/2020 8:36:14 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/19/2020 3:30:00 PM  
**End:** 2/19/2020 4:00:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/20/2020 8:39:46 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/21/2020 3:00:00 PM  
**End:** 2/21/2020 3:30:00 PM  
**Recurrence:** (none)

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/20/2020 8:42:44 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**Subject:** FW: 2/19 WEDNESDAY HOMEWORK - INTERNAL CONFIDENTIAL  
**Attachments:** 8.29.19\_H.Wimmer\_Amer.LungAssc.\_Vaping Lung Illness\_2019-3455-INCOMING.pdf; 2019-3455 Harold Wimmer\_Amer.Lung.Assc\_Vaping Pulmonary-OESedits-CTP Cleared\_2.12.20.docx; Rare Disease Day 2020 remarks.1.docx; Meeting prep sheet FDA Rare Disease Day Feb 24 2020.docx; Hahn Commissioned Corps all hands - Feb 21.docx; 20200219\_Readout FIB SMH ASPR SOC - OCC - AA cleared.docx

Just checking to see if you have had a chance to review the below docs?

**From:** Rom, Colin  
**Sent:** Wednesday, February 19, 2020 4:57 PM  
**To:** 'Hahn, Stephen' <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Subject:** 2/19 WEDNESDAY HOMEWORK - INTERNAL CONFIDENTIAL

Dr. Hahn, attached are the following for your review this evening:

- Letter for your review and signature in response to a note from Harold Wimmer, President and CEO of the American Lung Association, regarding the reported deaths and injuries from the use of e-cigs and vaping products.
- Draft remarks for Rare Disease Day 2020, this includes Amy's draft remarks for opening of the morning session.
- Talkers for the PHS all hands meeting on Friday
- FDA in Brief—Readout of Briefing in Secretary Operations Center

Have a good evening!



**ITEMS FOR YOUR REVIEW**

**Action:** **ITEM #1: Letter-- Harold Wimmer, President and CEO of the American Lung Association, Review and regarding the reported deaths and injuries from the use of e-cigs and vaping products**

Sign By

9:00am

Thursday



   
8.29.19\_H.Wimm... 2019-3455 Harold  
Lung Illness\_201... Wimmer\_Amer.L...

**Action:** **ITEM #2: Draft Remarks for Rare Disease Day 2020**

Edit By

9:00am

Thursday

   
Rare Disease Day Meeting prep sheet  
2020 remarks.1... FDA Rare Disea...

**Action:** **ITEM 3#: Draft Talking Points for Commission Corps All Hands**

Edit By

9:00am

Thursday

  
Hahn  
Commissioned C...

Action: **ITEM #4: FiB—Readout of Briefing in Secretary Operations Center**

Review by

9:00am

Thursday



20200219\_Read...  
FIB SMH ASPR ..

Thanks!

**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 2/20/2020 10:07:13 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: Pink Sheet | Today's News & Analysis

Yes – I'll look into it

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Thursday, February 20, 2020 8:44 AM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** FW: Pink Sheet | Today's News & Analysis

(b)(5)

Sound OK?

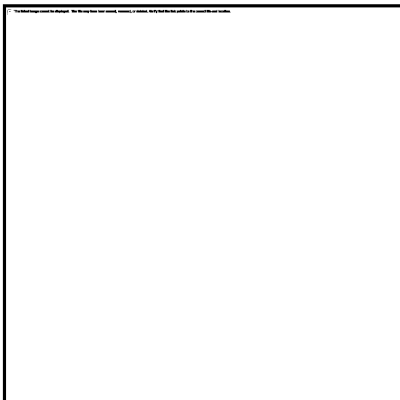
---

**From:** Pink Sheet <alert@mail.pharmaintelligence.informa.com>  
**Reply-To:** "Webpubs Alerts (Pink)" <reply-fe8717757c61017b72-311\_HTML-168568851-6418390-102@mail.wardsintelligence.informa.com>  
**Date:** Wednesday, February 19, 2020 at 7:03 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Pink Sheet | Today's News & Analysis

[View our online version](#)

19 Feb 2020

[Free Trial](#) | [Subscribe](#) | [Contact Us](#)



### DAILY ALERT

We want your feedback - Take part in our content and delivery survey by clicking here. Get the chance to win 1 of 4 Amazon gift vouchers worth £100 each just by taking part!

ADVERTISEMENT



## LATEST FROM PINK SHEET

---

### ANALYSIS

#### **Could ICER Outreach To US FDA Lead To Better Cost Effectiveness Analyses?**

To aid its value assessments, ICER is interested in helping FDA understand the importance of patient-relevant outcomes and consistent endpoints...

---

### NEWS

#### **Pfizer Warns Doctors About Blood Clot Risk With Xeljanz**

Now that the European Medicines Agency has finalized its formal safety review procedure into Xeljanz, Pfizer is telling health care...

---

### ANALYSIS

#### **Priority Review Voucher Programs Poised For US Legislative Attention In 2020**

Unless reauthorized by Congress, the rare pediatric disease program will begin to expire in September; renewal could bring bigger changes...

---

ADVERTISEMENT



### NEWS

#### **Two Companies, Two BARDA Contracts, Two Approaches To Coronavirus**

Sanofi follows Janssen in teaming up with HHS' BARDA to develop a COVID-19 vaccine; using technology platform of its Flublok...

---

### NEWS

#### **India Proposes Tiered Approach To Oversee Genome Editing**

India has proposed three categories for grouping genetically edited organisms based on the complexity of modifications.

---

### NEWS

#### **US/India Operation Intercepts Unapproved Drugs, Drug/Device Products**

Nearly 500 shipments of illegal and unapproved prescription drugs and combination medical devices were seized at US borders thanks to...

---

### NEWS

#### **Biogen's Recipe For Success In Knowledge Management**



Biogen's "recipe-driven qualification" knowledge management program standardizes data collection and reporting in the laboratory, with efficiency gains of 66%.

**NEWS**

**First African Approvals For Merck's Ebola Vaccine**

Regulators have pulled out all the stops in their efforts to get the Ebola vaccine to the marketing authorization stage...

**NEWS**

**New Filings At The EMA**

New medicines under evaluation at the European Medicines Agency.

**FROM THE *IN VIVO* ARCHIVES**

Please enjoy this article from our sister publication *In Vivo*.

**Regular Acceptance Of Simulation Studies More Likely In 2020s**

Lyon, France-based Novartis is developing a user-facing technology to run in silico studies, a method it expects to cut development costs and improve trial success rates. But acceptance of "new" data types is often a concern for drug developers, despite world-leading regulatory bodies stating their desire for 21st century approaches.

**PLANNING FOR REGULATORY VARIATION IN NDA TO BLA TRANSITIONS**

March 23, 2020 is the deadline for biological products approved in the US as New Drug Applications (NDAs) to transition to Biologics License Application (BLA) approvals as per the Biologics Price Competition and Innovations Act of 2009. Examine these changes, which affect NDAs for insulins, human growth hormones, and other proteins authorized under Section 505 of the FDCA. Read more.

PHARMINT

ADVERTISEMENT



Sent to sh1@fda.hhs.gov. You are receiving this email as a Pink Sheet subscriber. If you are not a subscriber or do not have your password, call US Support at +1 888-670-8900 (toll-free) or 1 908-547-2200 / UK support at + 44 (0) 20 7017 4161 or email [clientservices@pharma.informa.com](mailto:clientservices@pharma.informa.com)

To ensure delivery please add [alert@mail.pharmaintelligence.informa.com](mailto:alert@mail.pharmaintelligence.informa.com) to your address book. To stop receiving this email, or to manage your email preferences, [click here](#)

● 2020 Informa plc. All rights reserved.

Pink Sheet is owned and operated by Informa plc ("informa") whose registered office is 5 Howick Place, London, SW1P 1WG. Registered in England and Wales. Number 3099067. UK VAT Group GB 365 4626 36



---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/20/2020 1:05:31 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; Apple, Matthew (OS); Callaghan-Arguelles, Christine B (OS); Harrison, Brian (OS); Mango, Paul (OS); Puesan, Cesar (OS); Stecker, Judy (OS); Tignor, Beth (OS); Hahn, Stephen; Sheehy, Janice; Kadlec, Robert P (OS); Ford-Barnes, Arwenhithia (OS); Redfield, Robert R (CDC); Williams, Teresa (CDC); Gershman, Lynn E (CDC); Conrad, Patricia L (NIH); Fauci, Anthony S (NIH); Watters, Sam W (OS); Morse, Sara N (OS); Pence, Laura (OS)  
**Subject:** AMA Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce  
**Location:** 615-f  
**Start:** 2/24/2020 3:00:00 PM  
**End:** 2/24/2020 3:30:00 PM  
**Show Time As:** Tentative

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

sa

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/20/2020 1:09:18 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) (OS/IOS) (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]

**Subject:** AMA Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

**Start:** 2/26/2020 12:15:00 PM

**End:** 2/26/2020 1:00:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

sa

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/20/2020 1:43:02 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]  
**CC:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: FYSA: Supply chain updates

Thanks, Denise

---

**From:** Denise Hinton <Denise.Hinton@fda.hhs.gov>  
**Date:** Thursday, February 20, 2020 at 6:42 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** Anna Abram <Anna.Abram@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FYSA: Supply chain updates

Good morning, Dr. Hahn.

Please see the updates below for your situational awareness. The email has been cleared by Emily for your review. Anna planned to send to you as well, so I apologize if duplicative.

Thank you,

Denise

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Date:** February 19, 2020 at 7:31:30 PM EST  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Subject:** Supply chain updates

Hi Keagan, Anna, and Denise,

Just in case helpful for situational awareness, following are some supply chain updates from today. Also, Dr. Hahn seemed interested in (b)(5) during yesterday's AEG meeting, so we just wanted to make sure you had the links if needed.

(b)(5)

**(b)(5)**

**(b)(5)**

Have a nice evening,  
Brooke

Brooke Courtney, JD, MPH  
Senior Regulatory Counsel  
Office of Counterterrorism and Emerging Threats (OCET)  
Office of the Commissioner  
U.S. Food and Drug Administration  
301-796-0376 (office) **(b)(6)** (cell)  
[brooke.courtney@fda.hhs.gov](mailto:brooke.courtney@fda.hhs.gov)



---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/21/2020 1:34:32 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**Subject:** Fwd: FOR YOUR REVIEW ASAP: all hands email on outbreak response  
**Attachments:** All hands email COVID for Commissioner.docx  
**Importance:** High

Dr Hahn— please review ASAP when you have a sec

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Date:** February 21, 2020 at 12:33:45 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>  
**Subject:** FOR YOUR REVIEW ASAP: all hands email on outbreak response  
**Importance:** High

For your review as soon as you get the chance. We plan to send out today on your behalf. Laura is coordinating with ASPA to make sure they are aware. Thank you.

**From:** Christ, Katelyn E. EOP/NSC (b)(6)  
**Sent:** 2/21/2020 1:35:28 PM  
**To:** Christ, Katelyn E. EOP/NSC (b)(6); Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e64323944161a994c2086b645f4c-HHS-atb6-cd]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; FAULKNER, CHARLES (b)(6); uyen.dinh (b)(6); Kennedy, Wend (b)(6); Lange, John (b)(6); Ciccone, Christine (b)(6); Kaldahl, Ryan M (b)(6); Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Giannangeli, Giulia R (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Planning, David M. EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Kelly, Alison (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=881a7b1c2b714af78194995c288bea95-HHS-ayk7-cd]; Killion, William (b)(6); Nichols, Jennifer L (b)(6); Yaworske, Jason A. EOP/OMB (b)(6); Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; McKenna, Michael A. EOP/WHO (b)(6); Boney, Virginia M. EOP/WHO (b)(6); Swonger, Amy H. EOP/WHO (b)(6); Sugarman, AJ J. EOP/WHO (b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); KWESKIN, BENJAMIN (b)(6); Moore, Jessica L (b)(6); Cantrell, Benjamin B. EOP/OVP (b)(6); Wolfe, William E (b)(6); credmon@usaid.gov; ccole@usaid.gov; Rose, Jay E. EOP/NSC (b)(6); Serna, Christina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4da9a12770147b1a2967a9a9e7884f3-HHS-yyh9-cd]; Bulgrin, Julie K. EOP/NSC (b)(6); Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Kehoe, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e89758c5888c4d3986fdf1a861aff27b-HHS-Brian.K]; Delaney, William (USMS) [William.Delaney@usdoj.gov]; Rault, Nick M. EOP/NSC (b)(6); KASPER, JOSEPH (b)(6); Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; DL NSC Legislative (b)(6); Shwedo, Eric P COL USARMY OSD OASD LA (USA) (b)(6); skorde@usaid.gov; Leong, Rachel M. EOP/WHO (b)(6); Braid, James C. EOP/OMB (b)(6); Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; ryan.crumpler (b)(6); dino.carluccio (b)(6); MOTBOW (b)(6)

**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

**Subject:** All Senators briefing  
**Location:** SVC-217  
**Start:** 2/25/2020 8:00:00 AM  
**End:** 2/25/2020 9:00:00 AM  
**Show Time As:** Busy

As you know (b)(5)  
(b)(5)

**From:** Christ, Katelyn E. EOP/NSC (b)(6)  
**Sent:** 2/21/2020 1:35:28 PM  
**To:** Christ, Katelyn E. EOP/NSC (b)(6); Brand, Anstice M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4769e64323944161a994c2086b645f4c-HHS-atb6-cd]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; FAULKNER, CHARLES (b)(6); uyen.dinh (b)(6); Kennedy, Wendy (b)(6); Lange, John (b)(6); Ciccone, Christine (b)(6); Kaldahl, Ryan M (b)(6); Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Giannangeli, Giulia R (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Planning, David M. EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Kelly, Alison (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=881a7b1c2b714af78194995c288bea95-HHS-ayk7-cd]; Killion, William (b)(6); Nichols, Jennifer L (b)(6); Yaworske, Jason A. EOP/OMB (b)(6); Tourk, Nancy R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdb086e24ad14975bcc32097b68271fb-HHS-wxk8-cd]; McKenna, Michael A. EOP/WHO (b)(6); Boney, Virginia M. EOP/WHO (b)(6); Swonger, Amy H. EOP/WHO (b)(6); Sugarman, AJ J. EOP/WHO (b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); KWESKIN, BENJAMIN (b)(6); Moore, Jessica L (b)(6); Cantrell, Benjamin B. EOP/OVP (b)(6); Wolfe, William E (b)(6); credmon@usaid.gov; ccole@usaid.gov; Rose, Jay E. EOP/NSC (b)(6); Serna, Christina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4da9a12770147b1a2967a9a9e7884f3-HHS-yyh9-cd]; Bulgrin, Julie K. EOP/NSC (b)(6); Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Kehoe, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e89758c5888c4d3986fdf1a861aff27b-HHS-Brian.K]; Delaney, William (USMS) [William.Delaney@usdoj.gov]; Rault, Nick M. EOP/NSC (b)(6); KASPER, JOSEPH (b)(6); Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; DL NSC Legislative (b)(6); Shwedo, Eric P COL USARMY OSD OASD LA (USA) (b)(6); skorde@usaid.gov; Leong, Rachel M. EOP/WHO (b)(6); Braid, James C. EOP/OMB (b)(6); Greaser, Jennifer L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6007c3bba4a1420bb704298c5e49f29b-HHS-cbx5-cd]; ryan.crumpler (b)(6); dino.carluccio (b)(6); MOTBOW (b)(6)  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

**Subject:** All Senators briefing  
**Location:** SVC-217

**Start:** 2/25/2020 8:00:00 AM  
**End:** 2/25/2020 9:00:00 AM  
**Show Time As:** Tentative

As you know, (b)(5)  
(b)(5)

**(b)(5)**

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/21/2020 4:42:39 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS (b)(6)@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9d9cf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]

**Subject:** AMA Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

**Start:** 2/24/2020 12:00:00 PM

**End:** 2/24/2020 12:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

**Call:** (b)(6)  
**Participant:** (b)(6)  
**Leader:** (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/21/2020 4:52:58 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Distribution: Summary of Issues - 2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting - February 7, 2020

thanks

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Friday, February 21, 2020 at 3:33 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** RE: Distribution: Summary of Issues - 2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting - February 7, 2020

Yes, Denise was there and Michael was on the phone.

(b)(5)

(b)(5)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Friday, February 21, 2020 1:50 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Distribution: Summary of Issues - 2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting - February 7, 2020

Were we represented?

---

**From:** "DLGDESK (HHS/ASPR/OPP)" <DLGDESK@hhs.gov>  
**Date:** Friday, February 21, 2020 at 1:48 PM  
**To:** "Stannard, Paula (OS)" <Paula.Stannard@hhs.gov>, "Agnew, Ann (OS)" <Ann.Agnew@hhs.gov>, "Trueman, Laura (OS)" <Laura.Trueman@hhs.gov>, Robert Kadlec <Robert.Kadlec@hhs.gov>, "Rowell, Scott (OS)" <Scott.Rowell@hhs.gov>, Jen Moughalian <Jen.Moughalian@hhs.gov>, "Arbes, Sarah C (OS)" <Sarah.Arbes@hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "Destro, Brenda (OS)" <Brenda.Destro@hhs.gov>, "Tobias, Constance (OS)" <Constance.Tobias@hhs.gov>, Brett Giroir <Brett.Giroir@hhs.gov>, "Severino, Roger (OS)" <Roger.Severino@hhs.gov>, Garrett Grigsby <Garrett.Grigsby@hhs.gov>, Bob Charrow <Robert.Charrow@hhs.gov>, "Grimm, Christi A (OIG)" <Christi.Grimm@oig.hhs.gov>, "Griswold, Nancy J (OS)" <Nancy.Griswold@hhs.gov>, "Rucker, Donald (OS)" <Donald.Rucker@hhs.gov>, "Johnson, Lynn (ACF)" <Lynn.Johnson@acf.hhs.gov>, "Robertson, Lance (ACL)" <Lance.Robertson@acl.hhs.gov>, "Khanna, Gopal (AHRQ)" <Gopal.Khanna@ahrq.hhs.gov>, Robert Redfield <olx1@cdc.gov>, Seema Verma <Seema.Verma@cms.hhs.gov>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, "Engels, Thomas J (HRSA)" <TEngels@hrsa.gov>, "Weahkee, Michael (IHS)" <Michael.Weahkee@ihs.gov>, "Collins, Francis S (NIH)" <collinsf@od.nih.gov>, "McCance-Katz, Elinore (SAMHSA)" <Elinore.Mccance-katz@samhsa.hhs.gov>, "Cochran, Norris (OS)" <norris.cochran@hhs.gov>, "Hall, Bill (OS)" <bill.hall@hhs.gov>, "Schuchat, Anne (CDC)" <acs1@cdc.gov>, "Jernigan, Daniel B (CDC)" <dbj0@cdc.gov>, "Patel, Anita (CDC)" <bop1@cdc.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Denise Hinton <Denise.Hinton@fda.hhs.gov>, "Fauci, Anthony S (NIH)" <afauci@niaid.nih.gov>, "Sherman, Susan (OS)" <Susan.Sherman@HHS.GOV>, "Shane.C.Steiner@uscg.mil" <Shane.C.Steiner@uscg.mil>, "thomas.p.mccaffery.civ@mail.mil" <thomas.p.mccaffery.civ@mail.mil>, "Caneva, Duane (DHS.GOV)"

<duane.caneva@hq.dhs.gov>, "Christopher.Krebs@cisa.dhs.gov" <Christopher.Krebs@cisa.dhs.gov>, "Walters, William (STATE.GOV)" <walterswa2@state.gov>, "Glenn, Robert (fema.dhs.gov)" <robert.glenn@fema.dhs.gov>, "Phillip Ferro (NSC)" <Phillip.j.ferro@nsc.eop.gov>, "Anthony.J.Ruggiero@nsc.eop.gov" <Anthony.J.Ruggiero@nsc.eop.gov>, "Louis.trioli@pacom.mil" <Louis.trioli@pacom.mil>, "Kim, Paul (VA.GOV)" <paul.kim@va.gov>, "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.gov>, "Yeskey, Kevin (OS)" <Kevin.Yeskey@hhs.gov>, "Bright, Rick (OS)" <Rick.Bright@hhs.gov>, "Phillips, Sally (OS)" <Sally.Phillips@hhs.gov>, "Falcon, Jessica (OS)" <Jessica.Falcon@hhs.gov>, "Wolf, Laura K (OS)" <Laura.Wolf@hhs.gov>, "Adams, Steven A (CDC)" <saa1@cdc.gov>, "DeBord, Kristin (OS)" <Kristin.DeBord@hhs.gov>, "Dodgen, Daniel (OS)" <Daniel.Dodgen@HHS.GOV>, "Waters, Cicely (OS)" <Cicely.Waters@hhs.gov>, "Roman-Stolte, Claudia (OS)" <Claudia.Roman-stolte@hhs.gov>, "Donnelly, Kelsey S (OS)" <Kelsey.Donnelly@hhs.gov>, "Marston, Hilary D (NIH)" <hilary.marston@nih.gov>, "Taitsman, Julie (OIG)" <Julie.Taitsman@oig.hhs.gov>, "Brown, Christopher (DOL.GOV)" <brown.christopher.k@dol.gov>, "Michael.Finn@trade.gov" <Michael.Finn@trade.gov>, "MargolisJA@state.gov" <MargolisJA@state.gov>, "mark.j.dole.mil@mail.mil" <mark.j.dole.mil@mail.mil>, Stephen Hahn <SH1@fda.hhs.gov>, "Chang, William (OS)" <William.Chang@hhs.gov>, "KAUSHIK, SANGEETA" <sangeeta.kaushik@hq.dhs.gov>, "Sweatt.Loren.E@dol.gov" <Sweatt.Loren.E@dol.gov>, "Robinson, Shante R (OS)" <Shante.Robinson@hhs.gov>, "Brassard, Lucy E (OS)" <Lucy.Brassard@hhs.gov>, "Farmer, William (OS)" <William.Farmer@hhs.gov>, "Tate, Anna (OS)" <Anna.Tate@hhs.gov>, "DLGDESK (HHS/ASPR/OPP)" <DLGDESK@hhs.gov>

**Cc:** "Holland, Tara (OS)" <Tara.Holland@hhs.gov>, "Bratcher-Bowman, Nikki (OS)" <nikki.bratcherbowman@hhs.gov>, "Bird, Catherine (OS)" <Catherine.Bird@hhs.gov>, "Kim, Shalley (OS)" <Shalley.Kim@hhs.gov>, "Friedrichs, Paul (MIL)" <paul.a.friedrichs.mil@mail.mil>, "Bartrum, John J (OS)" <John.Bartrum@hhs.gov>, "Blackwell, Joyce" <joyce.blackwell@HQ.DHS.GOV>, "Bailey, Angela" <angela.bailey@hq.dhs.gov>, "Chaleki, Tom" <Tom.Chaleki@HQ.DHS.GOV>, "Music, Francesca (MIL)" <francesca.c.music2.civ@mail.mil>, "Wombacher, Matthew" <Matthew.Wombacher@cisa.dhs.gov>, "OS Salesses, Robert" <Robert.g.salesses.civ@mail.mil>, "thomas.chaleki@hq.dhs.gov" <thomas.chaleki@hq.dhs.gov>, "Dorko, Jeffrey (fema.dhs.gov)" <Jeffrey.Dorko@fema.dhs.gov>, "julie.dunne@gsa.gov" <julie.dunne@gsa.gov>, "cchan@usaid.gov" <cchan@usaid.gov>, "mbeers@usaid.gov" <mbeers@usaid.gov>, "Hanretta, Kevin (VA.GOV)" <Kevin.hanretta@va.gov>, "David.Kless@dla.mil" <David.Kless@dla.mil>, "nathan.a.moore@uscg.mil" <nathan.a.moore@uscg.mil>, "peter.j.potochney.civ@mail.mil" <peter.j.potochney.civ@mail.mil>, "dinkelmanJ@state.gov" <dinkelmanJ@state.gov>, "Cooper, Kevin (OS)" <Kevin.Cooper@hhs.gov>, "Messonnier, Nancy E (CDC)" <nar5@cdc.gov>, "Dickey, Laura M RDML USCG (USA)" <laura.m.dickey.mil@mail.mil>, "Carlson, Eric J" <CarlsonEJ@state.gov>, "Pence, Laura (OS)" <Laura.Pence@hhs.gov>, "Bradsher, Kris (OS)" <Kris.Bradsher@hhs.gov>, "Schmalz, Jennifer (ACF)" <Jennifer.Schmalz@acf.hhs.gov>

**Subject:** Distribution: Summary of Issues - 2020 Novel Coronavirus Supply Chain Disaster Leadership Group Meeting - February 7, 2020

Dear Disaster Leadership Group (DLG) Members,

This email serves to transmit the attached Summary of Issues prepared for the 2020 Novel Coronavirus Supply Chain DLG convened on February 7, 2020. We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message.

Additionally, please be aware that ASPR is planning to hold a DLG on COVID-19 next week for senior leaders. An invitation for that meeting should be sent in the coming days.

Please forward any questions or concerns related to this document to me, the DLG Policy Lead for this forum at [Daniel.Dodgen@hhs.gov](mailto:Daniel.Dodgen@hhs.gov) and kindly cc: [DLGDESK@hhs.gov](mailto:DLGDESK@hhs.gov) on any communications.



Thank you,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

☐ (b)(6)

Daniel.Dodgen@HHS.Gov | [www.phe.gov](http://www.phe.gov)

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/21/2020 4:58:30 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS (b)(6)@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Maj]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcdd4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Grant, Natalie (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ae60ad2853843239a5dac94e5a71b1f-HHS-Natalie]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fc1b527694276af1ccdb7db495042-HHS-Brian.S]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Harder, Kristina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a27fdbe16947fcb4a0c7caad82aa32-HHS-Kristin]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; EDH (OS/IOS)



---

(Kenneth.Callahan@hhs.gov); Zebley, Kyle (HHS/OS/OGA); Elvander, Erika (OS/OGA); Shuy, Bryan (OS/ASPR/IO)  
(Bryan.Shuy@hhs.gov); Adams, Jerome (HHS/OASH); Stephen Hahn (sh1@fda.hhs.gov); Gershman, Lynn E.  
(CDC/DDPHSIS/OD)

ONLY THOSE ON THIS INVITE MAY CALL IN OR ATTEND.

PLEASE CALL IN EARLY SO YOU DO NOT INTERRUPT THE BRIEFING ONCE STARTED

Lead: OGA

(b)(6)

PLEASE BE SURE TO IDENTIFY YOURSELF UPON CALLING IN OR YOU WILL NOT BE ALLOWED TO PARTICIPATE

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/21/2020 5:00:38 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce  
**Location:** 615-f  
**Start:** 2/24/2020 12:00:00 PM  
**End:** 2/24/2020 12:30:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/21/2020 5:00:52 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 1/28/2020 3:30:00 PM  
**End:** 1/28/2020 4:00:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/21/2020 5:05:27 PM  
**To:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]  
**Subject:** Re: Welcome home and thank you

Terrific. Thanks

---

**From:** Anna Abram <Anna.Abram@fda.hhs.gov>  
**Date:** Wednesday, February 19, 2020 at 7:03 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Mark Abdo <Mark.Abdo@fda.hhs.gov>  
**Subject:** Fwd: Welcome home and thank you

Thought you would appreciate this note from one of our colleagues from our China office in reply to the notes we sent them today. Your outreach was appreciated!

---

**From:** Campbell, Raicine <Raicine.Campbell@fda.hhs.gov>  
**Date:** February 19, 2020 at 6:37:03 PM EST  
**To:** Abram, Anna <Anna.Abram@fda.hhs.gov>  
**Subject:** RE: Welcome home and thank you

Hi Anna,

Well received, and thanks to both you and Mr. Hahn for reaching out. We definitely have our hands full with this one, but I am confident with the well-rounded leadership and dedicated staff of our agency, we will all get through this together one step at a time.

Best,

*Raicine Campbell, MPH*

Investigator  
Office of International Programs  
U.S. Embassy Beijing,  
No. 55 An Jia Jou Road  
Beijing 100600, P.R. China  
Desk: 86-10-8531-3833  
BB: (b)(6)



---

**From:** Abram, Anna <Anna.Abram@fda.hhs.gov>

**Sent:** Wednesday, February 19, 2020 3:14 PM

**To:** Robertson, Rohn <Rohn.Robertson@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; Sutton, William <William.Sutton@fda.hhs.gov>; Mathern, Jennifer <Jennifer.Mathern@fda.hhs.gov>; Kambere, Marijo <Marijo.Kambere@fda.hhs.gov>; Sampson, Meisha <Meisha.Sampson@fda.hhs.gov>; Marrero, Felix <Felix.Marrero@fda.hhs.gov>; Hustedt, Joel <Joel.Hustedt@fda.hhs.gov>; Kuilan-Torres, Laurimer <Laurimer.Kuilan-Torres@fda.hhs.gov>; Shokatz, Nicole <Nicole.Shokatz@fda.hhs.gov>; Stephens, Roy <Roy.Stephens@fda.hhs.gov>; Chapman, Jonathan <Jonathan.Chapman@fda.hhs.gov>; Middendorf, Christopher <Christopher.Middendorf@fda.hhs.gov>; Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>; Robinson, Latasha A <Latasha.Robinson@fda.hhs.gov>; Campbell, Raicine <Raicine.Campbell@fda.hhs.gov>; Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>

**Cc:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

**Subject:** RE: Welcome home and thank you

Dear Colleagues,

I'd like to echo the Commissioner's note of gratitude for your hard work and dedication to FDA's critical public health mission. We have been thinking of each of you and your family as you have returned in recent days. FDA is grateful for your contributions in advancing our vital public health mission at home and abroad.

Thank you, again, for what each of you do to advance our public health mission.

Sincerely,

Anna K. Abram

Deputy Commissioner for Policy, Legislation, and International Affairs

---

**From:** A Message from the Commissioner <message@fda.hhs.gov>

**Sent:** Wednesday, February 19, 2020 5:09 PM

**To:** Robertson, Rohn <Rohn.Robertson@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; Sutton, William <William.Sutton@fda.hhs.gov>; Mathern, Jennifer <Jennifer.Mathern@fda.hhs.gov>; Kambere, Marijo <Marijo.Kambere@fda.hhs.gov>; Sampson, Meisha <Meisha.Sampson@fda.hhs.gov>; Marrero, Felix <Felix.Marrero@fda.hhs.gov>; Hustedt, Joel <Joel.Hustedt@fda.hhs.gov>; Kuilan-Torres, Laurimer <Laurimer.Kuilan-Torres@fda.hhs.gov>; Shokatz, Nicole <Nicole.Shokatz@fda.hhs.gov>; Stephens, Roy <Roy.Stephens@fda.hhs.gov>; Chapman, Jonathan <Jonathan.Chapman@fda.hhs.gov>; Middendorf, Christopher <Christopher.Middendorf@fda.hhs.gov>; Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>; Robinson, Latasha A <Latasha.Robinson@fda.hhs.gov>; Campbell, Raicine <Raicine.Campbell@fda.hhs.gov>; Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>

**Cc:** Abram, Anna <Anna.Abram@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

**Subject:** Welcome home and thank you



From the Desk of  
the Commissioner



U.S. FOOD & DRUG  
ADMINISTRATION

---

Dear Colleagues,



I want you to know that since the outbreak of COVID-19, all of you have been on my mind, and on the minds of many FDA leaders. We are all glad that you're back safely. I am certain the past few weeks have been disruptive and hope that you and your families are settling in. Please know that the Agency is here to support you.

Deputy Commissioner Abram and Mark Abdoo have briefed me on the work of the Office of Global Policy and Strategy and the importance of our overseas presence. I understand the importance of our foreign offices and am glad we have staff like you abroad and admire the work you do to keep Americans safe.

On a personal note, I am no stranger to China. In fact, in my previous jobs, I've spent quite a bit of time there. I know how crowded its cities are and I must say seeing media pictures of deserted streets in Beijing was truly eerie.

Coronavirus reminds us that a global organization like FDA faces many challenges. We will make it through this one stronger and more resilient.

Thank you for your dedication to FDA's public health mission. Your spirit and strength show all of FDA – and the American people – what public serve truly means.

Sincerely,

**Stephen M. Hahn, M.D.**  
**Commissioner of Food and Drugs**



**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/21/2020 5:15:39 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) [OS/IOS]; (b)(6) [OS/IOS]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]

**Subject:** AMA call with Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

**Start:** 2/24/2020 12:00:00 PM

**End:** 2/24/2020 12:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

**Call:** (b)(6)  
**Participant:** (b)(6)  
**Leader:** (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----

---

**From:** Robert Levitt; (b)(6)  
**Sent:** 2/21/2020 5:28:35 PM  
**Subject:** Dr. Levitt's Update on COVID-19 for 21 Feb 2020

Dear All,

**WSJ Ed/Op** by Dr. Gottlieb, formerly of FDA, asks why U.S. has so few confirmed COVID-19 cases: <https://www.wsj.com/articles/why-does-the-u-s-have-so-few-confirmed-coronavirus-cases-11582241112>. Title doesn't seem to fit the article in my opinion. Maybe federal officials are doing a great job is my answer to the title question. Authors offer 5 suggestions to detect more undetected cases.

**SHEA** has produced a fact sheet for hospitals to distribute to staff, faculty to keep them up to date on COVID-19. See: <http://shea-online.org/index.php/practice-resources/priority-topics/emerging-pathogens/novel-coronavirus-2019-2019-ncov-resources/33-priority-topics/emerging-pathogens/722-novel-coronavirus-2019-2019-ncov-faq>

It's very good. Thank you **SHEA**.

**The Scientist** has an article on **how COVID-19 spreads person to person which is excellent**: [https://www.the-scientist.com/news-opinion/how-covid-19-is-spread-67143?utm\\_campaign=TS\\_DAILY%20NEWSLETTER\\_2020&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=83699238&hsenc=p2ANgtz-\\_vgpXvarBbWD7p8AtVABHol8048jLsb96gZeeobCfAgsMC9cHcStlNR09MB1ijmK5Zuf6LJOCVfzJb0i5i\\_em0g2o4mQ&hsmi=83699238](https://www.the-scientist.com/news-opinion/how-covid-19-is-spread-67143?utm_campaign=TS_DAILY%20NEWSLETTER_2020&utm_source=hs_email&utm_medium=email&utm_content=83699238&hsenc=p2ANgtz-_vgpXvarBbWD7p8AtVABHol8048jLsb96gZeeobCfAgsMC9cHcStlNR09MB1ijmK5Zuf6LJOCVfzJb0i5i_em0g2o4mQ&hsmi=83699238)

Dr. Fauci said the same causes when he and Dr. Kadlec gave interviews on CSPAN.

SHEA is producing Webinars on COVID-19 next Monday and the beginning of March. See: [https://contentsharing.net/actions/email\\_web\\_version.cfm?ep=N8\\_79D-p--sUGwsLnJINQYJ2WCRJVBC50v0edxZzIys4gc5ecKJXJUjXWb2IIRobUPBSGfgV3vdDj2wz4lilGalwwvRp4adte53pVIbo5Mr7soEzj\\_KWiRMTx-mrjdy5](https://contentsharing.net/actions/email_web_version.cfm?ep=N8_79D-p--sUGwsLnJINQYJ2WCRJVBC50v0edxZzIys4gc5ecKJXJUjXWb2IIRobUPBSGfgV3vdDj2wz4lilGalwwvRp4adte53pVIbo5Mr7soEzj_KWiRMTx-mrjdy5)

**NYT Ed/Op** on how some Not For Profit Hospitals make tons of money by stretching the meaning of 'community benefits'. It's within the law, but isn't really 'charity care' which was the intent of the law. **Perhaps Not For Profit hospitals can help more in the response to COVID-19 by asking NIAID, CDC, NIH, BARDA how they can help right now.** See: [https://www.nytimes.com/2020/02/20/opinion/nonprofit-hospitals.html?te=1&nl=david-leonhardt&emc=edit\\_ty\\_20200221&campaign\\_id=39&instance\\_id=16166&segment\\_id=21486&user\\_id=e37b7ca2e8bae8d104574a7b4a01f953&regi\\_id=6869412220200221](https://www.nytimes.com/2020/02/20/opinion/nonprofit-hospitals.html?te=1&nl=david-leonhardt&emc=edit_ty_20200221&campaign_id=39&instance_id=16166&segment_id=21486&user_id=e37b7ca2e8bae8d104574a7b4a01f953&regi_id=6869412220200221)

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

Sent from Outlook

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/21/2020 6:26:57 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb6164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]  
**Subject:** FDA Heads Up for HHS NN - 2/24/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/24/20:

- **FDA to provide update on response to COVID-19**

On Monday, FDA is expected to communicate on its work in response to the novel coronavirus outbreak (COVID-19), particularly with more information on FDA's inspection process.

- **FDA to enhance functionality of Purple Book to support transparency in biosimilars**

On Monday, FDA is expected to improve access to The Purple Book, otherwise known as the Database of FDA-Licensed Biological Products, by upgrading from the current table format to a searchable, public-facing online database, plus adding more content.

- **FDA to approve first generic of Daraprim tablets (confidential)**

On Monday, FDA is expected to approve the first generic of Daraprim (pyrimethamine) tablets for the treatment of toxoplasmosis (an infection caused by the parasite *Toxoplasma gondii*) when used with a sulfonamide (a group of medicines used to treat bacterial infections). Daraprim was originally approved in 1953.

- **FDA to issue final testing results of talc-containing cosmetic products**

On Monday, FDA will issue its final report and data table from the agency's year-long sampling assignment of testing talc-containing cosmetic products for the presence of asbestos. All positive results have already been made public. The final report will detail the negative results found as well.

- **FDA to hold public meeting on rare diseases**

On Monday, FDA will hold a public meeting and opportunity for public comment on rare disease product development, leading up to Rare Disease Day 2020 later this month. The meeting will take place at FDA headquarters in Silver Spring.

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/21/2020 6:28:46 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

---

**CC:** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]  
**Subject:** Canada, Lebanon report Iran-linked COVID-19 cases as concerns rise

<http://www.cidrap.umn.edu/news-perspective/2020/02/canada-lebanon-report-iran-linked-covid-19-cases-concerns-rise>



**From:** vinu arumugham (b)(6)  
**Sent:** 2/22/2020 2:58:45 AM  
**To:** zaoutis (b)(6); Banerjee.Ritu (b)(6); ebarnett (b)(6); jcampbel (b)(6); Kourtis, Athena P (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cf7c416b4cd4d17aad245b41c1a7b8d-HHS-apk3-cd]; noltd (b)(6); chris.nyquist (b)(6); Sarah.Brewer (b)(6); dkimberlin (b)(6); Hbernstein (b)(6); Cohn, Amanda C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4cbff30d34c4611a2e973fcb192de37-HHS-anc0-cd]; Farizo, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4e44a6d3b754a66ad321c00f9b1debd-Farizo]; Fischer, Marc (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d1ac80cb41e45058db9f58420cfa8cc-HHS-mxf2-cd]; natasha.halasa (b)(6); lakerley (b)(6); stevermerj (b)(6); kct9@cdc.gov; feemster (b)(6); Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissioner]; aljjr (b)(6); jason.smit (b)(6); Davey, Andrea (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb54896aa1a4c59b51aada1b0782874-HHS-Andrea.]; Herzog, Andrea (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b3841e34be0467581940cbbc8e20a2-HHS-AHerzog]; louiedrosa (b)(6); ekraus (b)(6); tshimabukuro@cdc.gov; ahoustor (b)(6); Advisory Committee on Immunization Practices (CDC) [acip@cdc.gov]; beth\_luthy (b)(6); stewarta (b)(6); kgaffney (b)(6); ttan (b)(6); cmeissner (b)(6); melinda.wharton@cdc.hhs.gov; Barbara.Mulach (b)(6); marion.gruber@hda.hhs.gov; Mcneil, Michael M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aca27008205042d688e0ff327633e1b9-HHS-mmm2-cd]; narayan.nair@hhs.gov; Secretary@HHS.gov; dssangiamo (b)(6); Helfgott (b)(6); richard.brasington (b)(6); M.Iversen (b)(6)  
**Subject:** 2019-nCoV/COVID-19 treatment; Vaccine injury table; Epitope database evidence; Ebola vaccine will cause rice allergy epidemic

IgE mediated sensitization to peptides that have homology to 2019-nCoV/SARS-CoV-2 peptides may contribute to disease severity. In that case, antihistamines and other allergy treatments such as mast cell stabilizers may help reduce infection severity.

A BLASTP analysis of 2019-nCoV/SARS-CoV-2 proteome against common vaccine antigens was performed. Preliminary results suggest that IgE mediated sensitization to common vaccine antigens can result in cross reactive immune responses to 2019-nCoV/SARS-CoV-2.

Please see details of the mechanisms here:

Influenza vaccines and dengue-like disease

<https://www.bmj.com/content/360/bmj.k1378/rr-15>

<https://www.quora.com/Why-was-the-flu-so-deadly-in-outbreaks-in-the-past-And-what-made-the-flu-become-less-deadly/answers/86456279>

Interestingly, CNN reports that the Shanghai Institute of Materia Medica and the Wuhan Institute of Virology, discovered that Shuanghuanglian (SHL) - a traditional Chinese herbal remedy, could "inhibit" the 2019-nCoV/SARS-CoV-2 infection.

<https://www.cnn.com/2020/02/01/asia/chinese-traditional-medicine-claims-coronavirus-intl-scli-hnk/index.html>

*Shuang-Huang-Lian Attenuates Airway Hyperresponsiveness and Inflammation in a Shrimp Protein-Induced Murine Asthma Model.*

<https://www.ncbi.nlm.nih.gov/pubmed/30713573>

SHL as described in the article above, can act as a mast cell stabilizer. So it is understandable that SHL can help in 2019-nCoV/SARS-CoV-2 infection for reasons I detailed above.

Increasing indoor temperature may be a relatively easy way to reduce transmission and reduce disease severity of 2019-nCoV/SARS-CoV-2 infection.

Of course this is in general a good idea even for influenza/common cold virus transmission.

---

Updated:

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020

Covering over 125 conditions

Latest version with hyperlinks, will open in your PDF application:

[https://zenodo.org/record/3647593/files/vbitr2\\_final.pdf?download=1](https://zenodo.org/record/3647593/files/vbitr2_final.pdf?download=1)

All versions: <https://doi.org/10.5281/zenodo.2582634>

---

"Scientists" at the global vaccine safety summit spill the beans: There is no science behind vaccine safety claims, it's a fairy tale.

The party is over folks.

<https://youtu.be/s2IujhTdCLE>

---

ERVEBO Ebola vaccine will create a rice allergy epidemic, add to numerous autoimmune diseases, cancer and make Ebola disease even more severe. Design for safety and vaccine safety regulation remain abject failures.

Incompetence or indifference?

<https://doi.org/10.5281/zenodo.3595020>

---

Analyzing 23000+ epitopes covering 82 autoimmune diseases in the Immune Epitope Database, 57% have only one and 78% have up to two amino acid residue differences compared to animal, fungal or plant peptides present in vaccines; an unmistakable signature of the role of vaccines in their etiologies

<https://doi.org/10.5281/zenodo.3603480>

**Analyzing 23000+ epitopes covering 82 autoimmune diseases in the Immune Epitope Database, 57% have only one and 78% have up to two amino acid residue differences compared to animal, fungal or plant peptides present in vaccines; an unmistakable signature of the role of vaccines in their etiologies**

## Lay summary

Proteins are a chain of amino acids. Proteins can have up to several hundred amino acids. Snippets of proteins (peptides), 7-15 amino acids in length are important in immunology. There are 20 types of amino acids. Each is assigned a letter (1 letter code).

Antibodies are proteins that can bind to peptides that have a specific amino acid sequence. Such a target peptide is known as an epitope. When an antibody binds to a peptide (which is part of a protein, which in turn may be part of a cell surface), it can trigger an immune attack on the cell. If the cell were a bacterium, the bacterium would be killed.

Humans (like all organisms) are made of numerous proteins (self proteins). So we have self-proteins, self-peptides and self-epitopes. In a healthy person, the body will not make antibodies that bind strongly to self-peptides (self-tolerance).

DNA is a chain of base-pairs. The DNA base-pair sequence determines the amino acid sequence in the protein produced. If there is a mutation that alters a single base-pair, the resulting protein will have a single amino acid that is altered. To prevent cancer, the immune system is capable of making antibodies against such altered peptides. Such antibodies can also weakly bind (cross react) to the unaltered normal peptide thus resulting in destruction of some healthy cells.

Say a normal protein has the following peptide (10 amino acids, each represented by its 1 letter code):

ALSTLVVNKI

Say DNA in a cell mutates due to a carcinogen exposure and it alters the protein thus resulting in this peptide with a single amino acid change:

ALSTLVVSKI

When the immune system makes antibodies targeted at ALSTLVVSKI (to attack the cell with the DNA mutation), the same antibodies can weakly bind to the normal ALSTLVVNKI peptide.

ALSTLVVNKI is an epitope associated with rheumatoid arthritis (RA).

So as a result of the immune system defending against cancer, the person can develop RA.

Now consider vaccines containing animal proteins. Animal proteins are very similar to human proteins, containing only occasional amino acid differences. An animal peptide could therefore have the ALSTLVVSKI sequence. Such a vaccine would fool the immune system into creating an anti-cancer immune response, creating antibodies targeted at ALSTLVVSKI. The result is vaccine induced RA.

Therefore one can predict that analyzing epitopes associated with autoimmune diseases, such single amino acid difference compared to animal peptides present in vaccines, would occur more frequently than can be expected merely by chance. The analysis confirms that this prediction is valid.

## Abstract

The National Institute of Allergy and Infectious Diseases (NIAID) sponsors the Immune Epitope Data Base (IEDB). IEDB contains epitopes identified from the medical literature and organized by diseases and categories of diseases. All epitopes (23000+) associated with 82 autoimmune diseases in humans were analyzed.

The role of animal, plant, fungal proteins contained in vaccines in the etiology of autoimmune diseases have been described in humans and animals. BLASTP was used to analyze IEDB derived epitopes for sequence alignment to animal, plant, fungal (APF) proteins present in vaccines and biologics. Specifically, the search was performed against bovine, chicken, porcine, guinea pig, African green monkey, Chinese hamster, murine, peanut, soy, wheat, corn, sesame and *Saccharomyces cerevisiae* proteomes.

The results show that 57% of epitopes differed by exactly one amino acid residue from an APF peptide. 78% of the epitopes differed by up to two amino acid residues from an APF peptide. The rest of the epitopes were either identical or differed by more than two amino acid residues.

A majority of IEDB epitopes analyzed were 9-mer peptides. Comparing randomly selected 9-mer human peptides with APF proteomes, the probability of single amino acid residue difference (SAARD) outcomes was derived. This was used to estimate the probability that actual IEDB SAARD alignments to APF peptides were merely a chance outcome. The estimates show that the probability that the observed IEDB alignments to APF being merely a chance outcome are vanishingly small. So the results make it absolutely clear that APF proteins in vaccines cause all these autoimmune diseases.

## Introduction

Vaccines contain thousands of residual animal, plant and fungal (APF) proteins from the manufacturing process (1–6). 293 chicken proteins were identified in the influenza vaccine (7), for example. Actin and vimentin proteins were detected in the Priorix Tetra vaccine (8). Immunization with homologous xenogeneic antigens resulting in autoimmune diseases has been known for at least 40 years (9). Vaccines that contain bovine proteins caused autoimmunity in dogs (10). We previously described the immunological mechanism involved in autoimmunity induction by immunization with homologous xenogeneic antigens (11).

Cancer cells have minor differences when compared to healthy cells. Due to mutation of the DNA encoding the proteins, cancer cells can display altered proteins on their surface. Healthy cancer defense mechanisms include immune responses directed at such altered proteins. Therefore an immune response directed against cancer cells always carries a risk of cross reactive immune responses against healthy cells displaying the unaltered protein. Therefore, cancer induced autoimmune responses are a consequence of normal, healthy immune system behavior.

Animal proteins have minor differences compared to human proteins. Peptides that are identical between humans and animals are unlikely to cause any problem due to strong self tolerance. However, peptides with one amino acid residue difference produce the strongest cross reactive immune responses (11). They are ideally suited to induce autoimmune diseases. Injecting animal proteins results in anti-cancer immune responses because the immune system perceives animal proteins as altered human proteins. Adjuvants in the vaccine boost this anti-cancer immune response. This artificial anti-cancer response directed at thousands of APF proteins in vaccines or biologics, therefore cross react and cause numerous autoimmune disorders.

For this reason, one can predict that single amino acid residue difference (SAARD) between autoimmune disease related epitopes in the IEDB and homologous APF peptides in vaccines, would occur at a higher probability than by mere chance. We perform a BLASTP analysis to verify.

## Methods

Basic local alignment search tool for proteins (BLASTP) (12), Universal Protein Resource (UniProt)(13) and the Immune Epitope Database (IEDB) (14) were used for bioinformatics analysis.

Specifically, the BLASTP sequence alignment of IEDB peptides was performed against bovine, chick, porcine, guinea pig, African green monkey, Chinese hamster, murine, peanut, soy, wheat, corn, sesame and *Saccharomyces cerevisiae* proteomes. Vaccines and biologics contain residual proteins from all these organism

due to media used to grow viruses or bacteria, recombinant cells/organisms used for protein expression or as excipients.

## Results

57% of IEDB peptides have a SAARD and 78% have up to two amino acid differences compared to animal, fungal or plant peptides present in vaccines.

## Discussion

Could this result be a chance occurrence?

A majority of IEDB epitopes analyzed were 9-mer peptides. Five thousand 9-mer peptides were chosen at random from the human proteome. BLASTP was run using these peptides to compare against each organism's proteome or a subset. This provides us the probability that randomly selected human peptides have an alignment providing a SAARD compared to peptides from these organisms. These are listed in table 1 under "Random SAARD alignment". Given this, we can compute the probability of the actual SAARD alignment to IEDB epitopes, occurring by chance. This is listed in table 1 under "Estimated probability of actual SAARD outcome occurring just by chance".

For a simple coin toss example, we would perform the calculation as follows:

Computing probability of say a 7 heads, 3 tails outcome of 10 trials of a fair coin:

$$\text{Probability} = (0.5^7) \times (0.5^3) \times 10! / (7! \times 3!)$$

Where:

0.5 is the probability of a head or tail outcome of a fair coin.

For an unfair coin, say probability of head outcome = 0.4 and tail outcome 0.6, we would have:

$$\text{Probability} = (0.4^7) \times (0.6^3) \times 10! / (7! \times 3!)$$

For the IEDB peptide probability analysis, the outcome is for 23192 trials (peptides).

The "head outcome" is the "Random SAARD alignment" entries in table 1. The "tail outcome" probability is 1-"head outcome".

Sample calculation for Chinese Hamster:

$$\text{Probability} = ((889/5000)^{4574}) \times ((4111/5000)^{18618}) \times 23192! / (4574! \times 18618!)$$

$$\text{Probability} = 1.488e-15$$

Where:  $889 \times 100 / 5000 = 17.8\%$  is the entry in Table 1 for Chinese Hamster. BLASTP analysis shows 889 SAARD out of 5000 peptides analyzed.

And,  $4574 \times 100 / 23192 = 19.7\%$  is the IEDB entry in Table 1 for Chinese Hamster. BLASTP analysis shows 4574 SAARD out of 23192 peptides analyzed.

So the 1.488e-15 value is the probability that we will have exactly 4574 SAARD alignments out of 23192 peptides. The probability goes down for all values > 4574. Conservatively, applying the same probability as for 4574, to all values > 4574, we can calculate the probability of the chance occurrence of 4574 or greater number of SAARD alignments as  $1.488e-15 \times 18618 = 27e-12$ , entry in table.

The Gnome calculator was used to perform these calculations and the results were verified using the Qalculate! calculator and WolframAlpha (15) since spreadsheets are unable to perform these calculations.

## Table 1

| Organism                                             | Random SAARD alignment Number of Peptides(%) | Actual (IEDB) SAARD alignment Number of Peptides (%) | Estimated probability of actual SAARD outcome occurring just by chance | Remarks                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------|----------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| African green monkey ( <i>Chlorocebus aethiops</i> ) | 26 (0.5)                                     | 420 (1.8)                                            | ~1.7e-96                                                               | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                                                                                     |
| Cow ( <i>Bos taurus</i> )                            | 936 (18.7)                                   | 4385 (18.9)                                          | ~1                                                                     | There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all cow proteins are present in the vaccines in equal amount is not true. We know that cow's milk, bovine gelatin, bovine serum albumin are used in vaccines. So these proteins and proteins present in tissues in the vicinity, are included in vaccines but other cow proteins may not be present. This is the more likely explanation. Please see Cow's milk entry below. |
| Cow's Milk ( <i>Bos taurus</i> )                     | 0 (0)                                        | 12 (0.05)                                            | 0                                                                      | Probability of this outcome occurring just by chance is 0. So these animal proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                                                                                                     |
| Chinese Hamster ( <i>Cricetulus griseus</i> )        | 889 (17.8)                                   | 4574 (19.7)                                          | ~27e-12                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, biologics caused these diseases.                                                                                                                                                                                                                                                                                                                           |
| Chicken ( <i>Gallus gallus</i> )                     | 536 (10.7)                                   | 3901 (16.8)                                          | <1e-100                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases. Unlike bovine, porcine and murine proteins, since chicken egg or embryo is used for vaccine manufacture, all chicken proteins can be present in vaccines.                                                                                                                                                                           |
| Guinea Pig ( <i>Cavia porcellus</i> )                | 837 (16.7)                                   | 4439 (19.1)                                          | ~1e-18                                                                 | Probability of this outcome occurring just by chance is vanishingly small. So these animal proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                                                                                     |
| Mice ( <i>Mus musculus</i> )                         | 940 (18.8)                                   | 4467 (19.3)                                          | ~1                                                                     | There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all mice proteins are present in biologics in equal amount is not true. We know that mice myeloma cells                                                                                                                                                                                                                                                                      |

| Organism                                  | Random SAARD alignment Number of Peptides(%) | Actual (IEDB) SAARD alignment Number of Peptides (%) | Estimated probability of actual SAARD outcome occurring just by chance | Remarks                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------|----------------------------------------------|------------------------------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                           |                                              |                                                      |                                                                        | are used in biologics. So these proteins and proteins present in tissues in the vicinity, are present in biologics but other mice proteins may not be present. This is the more likely explanation.                                                                                                                                                                                                           |
| Maize ( <i>Zea mays</i> )                 | 303 (6.1)                                    | 1667 (7.2)                                           | ~5e-9                                                                  | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                        |
| Peanut ( <i>Arachis hypogaea</i> )        | 223 (4.5)                                    | 1697 (7.3)                                           | ~79e-81                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                        |
| Yeast ( <i>Saccharomyces cerevisiae</i> ) | 64 (1.3)                                     | 828 (3.6)                                            | <1e-100                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these fungal proteins in vaccines, biologics caused these diseases.                                                                                                                                                                                                                                                             |
| Sesame ( <i>Sesamum indicum</i> )         | 155 (3.1)                                    | 1398 (6.0)                                           | <1e-100                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                        |
| Soy ( <i>Glycine max</i> )                | 215 (4.3)                                    | 1548 (6.7)                                           | ~86e-59                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                        |
| Pig ( <i>Sus scrofa</i> )                 | 963 (19.3)                                   | 4407 (19.0)                                          | ~1                                                                     | There are two possibilities. (1) This outcome occurred just by chance. (2) The assumption that all porcine proteins are present in the vaccines in equal amount is not true. We know that porcine gelatin is used in vaccines. So these proteins and proteins present in tissues in the vicinity are included in vaccines but other porcine proteins may not be present. This is the more likely explanation. |
| Wheat ( <i>Triticum aestivum</i> )        | 138 (2.8)                                    | 977 (4.2)                                            | ~18e-33                                                                | Probability of this outcome occurring just by chance is vanishingly small. So these plant proteins in vaccines, caused these diseases.                                                                                                                                                                                                                                                                        |

The calculations make it clear that the findings cannot be merely a chance outcome and that immunization against animal/plant/fungal antigens in the vaccines do cause these autoimmune diseases in the IEDB.

## Conclusion

Vaccines containing animal, plant or fungal proteins are extremely dangerous and cause numerous autoimmune diseases and cancer (16–19). All non-target proteins in vaccines must be immediately removed using processes such as affinity chromatography (20).

## References

1. Kattan JD, Cox AL, Nowak-Wegrzyn A, Gimenez G, Bardina L, Sampson HA, et al. Allergic reactions to diphtheria, tetanus, and acellular pertussis vaccines among children with milk allergy. *J Allergy Clin Immunol*. 2011;Conference(var.pagings):AB238.
2. Arumugham V. Oxford Vaccine Group Vaccine Knowledge Project's Vaccine Ingredient and vaccine safety misinformation exposed [Internet]. 2019 [cited 2019 Dec 11]. Available from: <https://doi.org/10.5281/zenodo.3477854>
3. National Academies of Sciences and Medicine E. Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy. Stallings VA, Oria MP, editors. Washington, DC: The National Academies Press; 2017.
4. Gardasil Package Insert [Internet]. Available from: <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf>
5. ENGERIX-B HIGHLIGHTS OF PRESCRIBING INFORMATION [Internet]. Available from: <https://www.fda.gov/media/79341/download>
6. Arumugham V, Trushin M V. Role of NMDA receptor autoimmunity induced by food protein containing vaccines, in the etiology of autism, type 1 diabetes, neuropsychiatric and neurodegenerative disorders [Internet]. *International Journal of Pharmaceutical Research*. 2019 [cited 2019 Apr 15]. p. 428–37. Available from: <https://doi.org/10.5281/zenodo.1463600>
7. Jacob L, Leib R, Ollila HM, Bonvalet M, Adams CM, Mignot E. Comparison of Pandemrix and Arepanrix, two pH1N1 AS03-adjuvanted vaccines differentially associated with narcolepsy development. *Brain Behav Immun*. 2015 Jul;47:44–57.
8. Corvelva. Vaccinegate:Study on the chemical composition profile of Priorix Tetra [Internet]. 2018 [cited 2019 Aug 24]. Available from: <https://drive.google.com/file/d/1cNtdBczAX1-xowPEDep1kZOjy84IypAB/view>
9. Arumugham V. Vaccination with bovine, chick, yeast antigens synthesizes cross-reactive antibodies targeting human acetylcholine receptor and MuSK protein to cause Myasthenia Gravis: Confirmed by natural experiment (VAERS data), bioinformatics, case reports, animal experiments and titer study [Internet]. 2019 [cited 2019 Sep 16]. Available from: <https://doi.org/10.5281/zenodo.3421558>
10. Hogenesch H, Azcona-Olivera J, Scott-Moncrieff C, Snyder PW, Glickman LT. Vaccine-induced autoimmunity in the dog. *Adv Vet Med*. 1999;41:733–47.



11. Arumugham V, Trushin M V. Cancer immunology, bioinformatics and chemokine evidence link vaccines contaminated with animal proteins to autoimmune disease: a detailed look at Crohn's disease and Vitiligo. *J Pharm Sci Res.* 2018;10(8):2106.
12. Altschul SF, Madden TL, Schäffer AA, Zhang J, Zhang Z, Miller W, et al. Gapped BLAST and PSI-BLAST: a new generation of protein database search programs. *Nucleic Acids Res.* 1997;25(17):3389–402.
13. UniProt: the universal protein knowledgebase. *Nucleic Acids Res.* 2017 Jan 4;45(D1):D158–69.
14. Vita R, Mahajan S, Overton JA, Dhanda SK, Martini S, Cantrell JR, et al. The Immune Epitope Database (IEDB): 2018 update. *Nucleic Acids Res. Oxford University Press;* 2019;47(D1):D339–43.
15. Wolfram|Alpha: Computational Intelligence [Internet]. [cited 2020 Jan 8]. Available from: <https://www.wolframalpha.com/>
16. Arumugham V. Vaccines and Biologics injury table based on mechanistic evidence – Mar 2019 [Internet]. 2019 [cited 2019 May 16]. Available from: <https://zenodo.org/record/2582635/files/viittoc0302http.pdf?download=1>.
17. Arumugham V. As predicted, animal protein containing biologics induce de novo autoimmune disorders [Internet]. 2019 [cited 2019 Dec 29]. Available from: <https://doi.org/10.5281/zenodo.3483322>
18. Arumugham V. Expanding ASIA to GAVIDOTTIR : GAmut of Vaccine Induced Damage emphasizing Off Target Immune Responses [Internet]. 2019 [cited 2019 Oct 23]. Available from: <https://doi.org/10.5281/zenodo.3478840>
19. Arumugham V. Role of anti-carbonic anhydrase 2 antibodies induced by vaccine antigens, in the etiology of acute myeloid leukemia and other malignancies [Internet]. 2019 [cited 2019 Nov 14]. Available from: <https://doi.org/10.5281/zenodo.3534442>
20. Zhao M, Vandersluis M, Stout J, Haupts U, Sanders M, Jacquemart R. Affinity chromatography for vaccines manufacturing: Finally ready for prime time? *Vaccine. Netherlands;* 2018 Apr;

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/22/2020 9:26:24 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

---

**CC:** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddb3e5f5eeb7f3d-Heather.Jan]; Finnen, April  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]

**Subject:** Updates case counts

As of 22 Feb at 2:03PM, 77,918 cases of COVID-19 have been reported with 2,361 deaths.

- 76,291 (98%) of cases are in China, with 63545 (83.0%) of those cases in Hubei Province.

433 cases now being reported in South Korea

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/22/2020 1:39:38 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Thx Heidi  
Tweets approved

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Date:** February 21, 2020 at 8:00:13 PM EST  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Actually, 2 more items for your review as soon as you get to them. Tweets are more time sensitive since some need to go over weekend. Statement will go out Monday.

1. COVID-19 inspections statement
2. Tweets for @SteveFDA and main handle

---

**From:** Rebello, Heidi  
**Sent:** Friday, February 21, 2020 5:40 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

We have a late edition coming your way... The statement on inspections related to outbreak. Will send that along soon; thank you.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Friday, February 21, 2020 5:29 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Dr. Hahn—

Only homework tonight is to review the below tweets for enhancements to the Purple Book by 9am Monday morning.

“We launched a new, modern version of the Purple Book today to increase transparency about biological products for patients and industry users. [link] [graphic]

The enhancements will meet the needs of a wide range of users – from patients to prescribers, researchers and industry representatives who may need more technical information.

This additional information should help facilitate the acceptance and use of biosimilars, which can increase competition, expanding choices for patients and potentially bring down prices on these important medicines.”

Have a great weekend!

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/23/2020 12:07:54 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Checking with ORA.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** February 22, 2020 at 1:48:20 PM EST  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

(b)(5)

S

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Date:** February 21, 2020 at 8:00:13 PM EST  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Actually, 2 more items for your review as soon as you get to them. Tweets are more time sensitive since some need to go over weekend. Statement will go out Monday.

1. COVID-19 inspections statement
2. Tweets for @SteveFDA and main handle

---

**From:** Rebello, Heidi  
**Sent:** Friday, February 21, 2020 5:40 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

We have a late edition coming your way... The statement on inspections related to outbreak. Will send that along soon; thank you.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>

**Sent:** Friday, February 21, 2020 5:29 PM

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>

**Subject:** 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Dr. Hahn—

Only homework tonight is to review the below tweets for enhancements to the Purple Book by 9am Monday morning.

“We launched a new, modern version of the Purple Book today to increase transparency about biological products for patients and industry users. [link] [graphic]

The enhancements will meet the needs of a wide range of users – from patients to prescribers, researchers and industry representatives who may need more technical information.

This additional information should help facilitate the acceptance and use of biosimilars, which can increase competition, expanding choices for patients and potentially bring down prices on these important medicines.”

Have a great weekend!

---

**From:** Robert Levitt; (b)(6)  
**Sent:** 2/23/2020 4:41:48 PM  
**Subject:** Dr. Levitt's Update on COVID-19 on 23 February 2020  
**Attachments:** Person to Person COVID-19.pdf; Clinical Features COVID-19.pdf; Another Clin Features COVID-19.pdf

Dear All,

**WSJ** this weekend has Review article on how data is now being shared about COVID-19 (I will use this term for the disease AND the virus causing the disease). Data is being shared faster than ever; scientists are working day and night and holding lab meetings at 3am. See:

<https://www.wsj.com/articles/sharing-data-faster-to-fight-an-epidemic-11582314253>

**The very latest reports are on public sites bioRxiv and medRxiv.** Note that these reports are not peer-reviewed. Copyright has been granted in perpetuity to these sites by authors, but not to individuals. So I will not display materials from these sites in my emails, but will refer readers to these sites.

**Washington Post** today reports that the **incubation period for COVID-19 can be longer than 14 days.** Two patients reported had incubation periods of 27 days and 38 days. In my opinion, U.S. should maintain quarantine of PUI on federal lands, such as military bases. No community will accept these PUI in community buildings. Costa Mesa, CA, is only the first to seek an injunction. See: [https://www.washingtonpost.com/world/asia\\_pacific/coronavirus-china-updates/2020/02/22/72dd19de-54ea-11ea-b119-4faabac6674f\\_story.html](https://www.washingtonpost.com/world/asia_pacific/coronavirus-china-updates/2020/02/22/72dd19de-54ea-11ea-b119-4faabac6674f_story.html)

**The Lancet** has 3 up to date articles on how the COVID-19 disease has presented in PRC. Each article has large numbers of patients in its Methods. Findings are similar in all the articles except whether steroids are helpful or harmful to recovery in serious disease. See pdfs above.  
Note person to person transmission is documented.

**medRxiv** has a report today that the clinical course of COVID-19 can be followed by serial CT. The CT severity matches the severity of inflammatory markers. See medRxiv today.

I wish to say publicly that I am proud that any not-for-profit hospital I have worked at in the past, currently, or in the future has maintained the highest ethics with respect to caring for charity patients.

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: Unsubscribe.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

Sent from Outlook



**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/23/2020 8:48:35 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7f7ebef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcdded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; White, Caroline (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a55bc6c3c0e84313889692f13a8bcf50-HHS-Carolin]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]

**Subject:** AMA call with Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** (b)(6)

**Start:** 2/24/2020 1:40:00 PM

**End:** 2/24/2020 2:10:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

Call (b)(6)  
Participant (b)(6)  
Leader (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----  
-----

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/23/2020 8:48:35 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS (b)(6)@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbddd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9d9cf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; White, Caroline (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a55bc6c3c0e84313889692f13a8bcf50-HHS-Carolin]; Chang, William (OS) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]

**Subject:** AMA call with Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

---

**Start:** 2/24/2020 1:40:00 PM  
**End:** 2/24/2020 2:10:00 PM  
**Show Time As:** Tentative

**Recurrence:** (none)

Call: (b)(6)  
Participant: (b)(6)  
Leader: (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----  
-----

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/23/2020 8:48:35 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bce26f9b3074-HHS-Laura.P]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcdded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]

**Subject:** AMA call with Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

**Start:** 2/24/2020 1:30:00 PM

**End:** 2/24/2020 2:00:00 PM

**Show Time As:** Tentative

---

Recurrence: (none)

Call: (b)(6)  
Participant: (b)(6)  
Leader: (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/23/2020 8:48:35 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9d9cf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]

**Subject:** AMA call with Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

**Start:** 2/24/2020 12:00:00 PM

**End:** 2/24/2020 12:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

**Call:** (b)(6)

**Participant:** (b)(6)

**Leader:** (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----



**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/23/2020 8:48:35 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6) @HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Hahn, Stephen (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; White, Caroline (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a55bc6c3c0e84313889692f13a8bcf50-HHS-Carolin]; Chang, William (OS) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]

**Subject:** AMA call with Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Location:** 615-f

---

**Start:** 2/24/2020 1:30:00 PM  
**End:** 2/24/2020 2:00:00 PM  
**Show Time As:** Busy

**Recurrence:** (none)

Call: (b)(6)  
Participant: (b)(6)  
Leader: (b)(6)

**Topic:** Prep session with the Secretary, Dr. Hahn, Dr. Fauci, Dr. Redfield, and Dr. Kadlec on coronavirus prior to his FY 2021 Budget hearing before Energy & Commerce

**Objective:** This will be an opportunity to prepare for the coronavirus component of the Energy & Commerce hearing

**AMA's Role:** To receive an update on the coronavirus and answer questions likely to be asked during the hearing

**Project Lead (IOS Senior Staff):** Laura Pence

**Working Project Lead (Name, Cell and email):** Courtney Bradway

**Is Conference Call Line needed?** N/A

**Who will initiate the conference call?** N/A

**Who will provide Briefing materials?** Courtney Bradway

**HHS Staff Attendees:** Drs. Fauci, Redfield, Kadlec, and Hahn. Sarah Arbes, Sara Morse, and Laura Pence will also be in attendance.

**External Attendees:** N/A

**Schedule Request Justification:** This is at the request of the Secretary. We would like to have an opportunity to prepare him specifically on the CoV component expected during his Energy & Commerce hearing. ASL requests 30-45 minutes on Monday or Tuesday, Feb. 25. The Energy & Commerce hearing is Feb. 26.

-----  
-----

---

**From:** Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]  
**Sent:** 2/23/2020 10:54:52 PM  
**To:** Friedrichs, Paul (MIL) (b)(6); Caneva, Duane (DHS.GOV) [duane.caneva@hq.dhs.gov]; Mecher, Carter (VA.GOV) [carter.mecher@va.gov]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]  
**CC:** Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]  
**Subject:** RE: (U) [Non-DoD Source] FW: COVID Modeling Parameters  
**Attachments:** smime.p7s

Paul thanks happy to assist however we can. Let me know what we can do to support. Best Bob

---

**From:** Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) (b)(6)  
**Sent:** Sunday, February 23, 2020 10:23 AM  
**To:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caneva, Duane (DHS.GOV) <duane.caneva@hq.dhs.gov>; Mecher, Carter (VA.GOV) <carter.mecher@va.gov>; Hahn, Stephen (FDA) <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>  
**Subject:** RE: (U) [Non-DoD Source] FW: COVID Modeling Parameters

CLASSIFICATION: UNCLASSIFIED

Dr. Kadlec

Thanks. DTRA team was also involved in this, so all of our modelers are now working with same data/assumptions. The speed and severity of spread in ROK and Italy in spite of strong public health infrastructure may shape what we anticipate will happen in the future. Can't overstate how grateful we are for the coordination and collaboration given the significant interest in understanding most likely case as we advise operational commanders about the risk to force and implications for DoD OCONUS and CONUS ops.

V/r

Paul

CLASSIFICATION: UNCLASSIFIED

**From:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>  
**Sent:** Sunday, February 23, 2020 10:12 AM  
**To:** Caneva, Duane (DHS.GOV) <duane.caneva@hq.dhs.gov>; Mecher, Carter (VA.GOV) <carter.mecher@va.gov>; Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) (b)(6); Hahn, Stephen (FDA) <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>  
**Subject:** [Non-DoD Source] FW: COVID Modeling Parameters

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

---

fysa

---

**From:** Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>  
**Sent:** Sunday, February 23, 2020 9:57 AM  
**To:** SOC ASPR SLT <SOC-ASPR-SLT@hhs.gov>  
**Cc:** OS Secretaries Operations Center <hhs.soc@hhs.gov>; SOC Leadership <mcbteamleads@HHS.GOV.onmicrosoft.com>;

SOC Information Management Section Chief (OS/ASPR) <SOC.IM@hhs.gov>; SOC Planning Section Chief (HHS/ASPR) <SOC.Plans@hhs.gov>

**Subject:** COVID Modeling Parameters

Dr Kadlec and ASPR SLT,

The ASPR Modeling Team in coordination with CDC did some updates to the modeling parameters from last week, to include Mr. Mango's request for seasonal flu comparison.

Attached for your awareness.

Sam

V/r,

Sam Imbriale, MPH

Director, Information Management Division

Director (Acting), Secretary's Operations Center

Cell: (b)(6)

Samuel.imbriale@hhs.gov < Caution-mailto:Samuel.imbriale@hhs.gov >

Sent from mobile device - please excuse typos.

---

**From:** Russ, Wanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2900752ACF81445785FB0F5B23C728C8-WRUSS]  
**Sent:** 2/24/2020 8:33:09 AM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** FW: COVID Modeling Parameters  
**Attachments:** Proposed Outbreak Scenarios COVID 19\_Release20200220.pdf

Share with Dr. Hahn.

---

**From:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>  
**Sent:** Sunday, February 23, 2020 10:12 AM  
**To:** Caneva, Duane (DHS.GOV) <duane.caneva@hq.dhs.gov>; Mecher, Carter (VA.GOV) <carter.mecher@va.gov>; Friedrichs, Paul (MIL) <paul.a.friedrichs.mil@mail.mil>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>  
**Subject:** FW: COVID Modeling Parameters

fysa

---

**From:** Imbriale, Samuel (OS/ASPR/SIIM) <Samuel.Imbriale@hhs.gov>  
**Sent:** Sunday, February 23, 2020 9:57 AM  
**To:** SOC ASPR SLT <SOC-ASPR-SLT@hhs.gov>  
**Cc:** OS Secretarys Operations Center <hhs.soc@hhs.gov>; SOC Leadership <mcbteamleads@HHS.GOV.onmicrosoft.com>; SOC Information Management Section Chief (OS/ASPR) <SOC.IM@hhs.gov>; SOC Planning Section Chief (HHS/ASPR) <SOC.Plans@hhs.gov>  
**Subject:** COVID Modeling Parameters

Dr Kadlec and ASPR SLT,

The ASPR Modeling Team in coordination with CDC did some updates to the modeling parameters from last week, to include Mr. Mango's request for seasonal flu comparison.

Attached for your awareness.

Sam

V/r,

Sam Imbriale, MPH  
Director, Information Management Division  
Director (Acting), Secretary's Operations Center  
Cell: (b)(6)  
Samuel.imbriale@hhs.gov

Sent from mobile device - please excuse typos.

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/24/2020 9:22:24 AM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review  
**Attachments:**

(b)(5)

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:22:04 AM EST  
**To:** (b)(6)@HHS.GOV (b)(6)@HHS.GOV  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

Mr. Secretary,  
My apologies for the delay. This email (sh1@fd.hhs.gov) is my direct contact email. We'll review the 3 memos ASAP.  
Steve

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:13:13 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

See below. You might want to email him your correct email too.

Sent from my iPhone

Begin forwarded message:

**From:** "Tobias, Lindsay" <Lindsay.Tobias@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:10:34 AM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>  
**Subject:** FW: nCoV WHTF Documents and Deliverables for Review

Looks like AMA may have used wrong email address for SH.

---

**From:** Russ, Wanda <Wanda.Russ@fda.hhs.gov>  
**Date:** February 24, 2020 at 8:48:42 AM EST

To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
Subject: FW: nCoV WHTF Documents and Deliverables for Review

FYI for Dr. Hahn.

From: (b)(6) (OS/IOS) (b)(6) @HHS.GOV>  
Sent: Saturday, February 15, 2020 2:31 PM  
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
Cc: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>  
Subject: Fwd: nCoV WHTF Documents and Deliverables for Review

(b)(5)

Thanks.  
AMA

Begin forwarded message:

From: "Ferro, Phil J. EOP/NSC" (b)(6)  
Date: February 14, 2020 at 5:40:34 PM EST  
To: (b)(6) (OS/IOS) (b)(6) @HHS.GOV>, AS2KTC <(b)(6)> "Biegun, Stephen E" (b)(6)  
"Bigley, Mark C. EOP/OMB" (b)(6) "Blair, Robert B. EOP/WHO"  
(b)(6) "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Butterfield, Nicholas W.  
EOP/WHO" (b)(6) "Campana, Alexandra D. EOP/WHO"  
(b)(6) "Cetron, Marty (CDC/DDID/NCEZID/DGMQ)" <mzc4@cdc.gov>, "Chafin, Kelly  
(EOP.GOV)" (b)(6) "Conant, Ann M. EOP/OMB" (b)(6) "Conley, Sean  
P. CDR USN WHMO/WHMU" (b)(6) "Conrad, Patricia (NIH/NIAID) [E]" (b)(6)  
"Davis, May M. EOP/WHO" (b)(6) "Ditto, Jessica E. EOP/WHO" <(b)(6)>  
DL Chief of Staff Office (b)(6) "O'berry, Donna (DOT.GOV)" <donna.o'berry@dot.gov>,  
"Duffey, Michael P. EOP/OMB" (b)(6) "Eisenberg, John A. EOP/WHO"  
(b)(6) "Fabina, Lauren C. EOP/NSC" (b)(6) "Fauci, Anthony  
(NIH/NIAID) [E]" (b)(6) "Ferro, Phil J. EOP/NSC" (b)(6) "Grogan, Joseph J.  
EOP/WHO" (b)(6) "Hemme, Jake W. EOP/NSC" (b)(6)  
"Hennessey, Millicent S. EOP/NSC" (b)(6) "Hoelscher, Douglas L. EOP/WHO"  
(b)(6) "Kan, Derek T. EOP/OMB" <(b)(6)>  
"Kenneth.p.rapuano.civ" (b)(6) <Kenneth.p.rapuano.civ (b)(6)> "Liddell, Christopher P. EOP/WHO"  
(b)(6) "Miller, Julie L. EOP/OMB" (b)(6) "Mulvaney, Mick M.  
EOP/WHO" (b)(6) "OS Salesses, Robert" (b)(6) "Pataki, Tim A.  
EOP/WHO" (b)(6) "Pottinger, Matthew F. EOP/WHO" (b)(6) "Riggs,  
Charlotte R. EOP/WHO" (b)(6) "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Kadlec,  
Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Ruggiero, Anthony J. EOP/NSC" (b)(6)  
"Scher, Adam A. EOP/OMB" (b)(6) "Shellooe, Ryan P. EOP/NSC"  
(b)(6) "Sinclair, Michael R. EOP/NSC" (b)(6) "Szabat, Joel (OST)"  
<Joel.Szabat@dot.gov>, "Troye, Olivia EOP/NSC" <(b)(6)> "Williams, Michael B. EOP/WHO"  
(b)(6) "Woolfolk, Jon J. EOP/OVP" <(b)(6)>  
Subject: nCoV WHTF Documents and Deliverables for Review

Good Afternoon WHTF,

(b)(5)

Please find the following documents attached for consideration by the TF. If amenable to the group, we would propose discussion by the TF at a future date.

(b)(5)

Currently, there are no TF calls scheduled Saturday – Monday.

Best Regards,

Phil

Philip J. Ferro, PhD, MS  
Director for Countering Biological Threats  
National Security Council

202.456.1222 (O) (b)(6) (cell)

(b)(6)



---

**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 2/24/2020 9:32:04 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: nCoV WHTF Documents and Deliverables for Review

Yes – will do

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 9:23 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

+Anand

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:20:29 AM EST  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: nCoV WHTF Documents and Deliverables for Review

Can you have folks review and get back to me with their comments? Anand and Keagan, can you coordinate?

Thx

S

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:13:13 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

See below. You might want to email him your correct email too.

Sent from my iPhone

Begin forwarded message:

**From:** "Tobias, Lindsay" <Lindsay.Tobias@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:10:34 AM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>  
**Subject:** FW: nCoV WHTF Documents and Deliverables for Review

Looks like AMA may have used wrong email address for SH.

**From:** Russ, Wanda <Wanda.Russ@fda.hhs.gov>  
**Date:** February 24, 2020 at 8:48:42 AM EST  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** FW: nCoV WHTF Documents and Deliverables for Review

FYI for Dr. Hahn.

**From:** AMA2 (OS/IOS) (b)(6) @HHS.GOV>  
**Sent:** Saturday, February 15, 2020 2:31 PM  
**To:** Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Harrison, Brian (OS) <Brian.Harrison@hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

(b)(5)

Thanks.  
AMA

Begin forwarded message:

**From:** "Ferro, Phil J. EOP/NSC" <(b)(6)>  
**Date:** February 14, 2020 at 5:40:34 PM EST  
**To:** (b)(6) OS/IOS (b)(6) @HHS.GOV>, AS2KTC (b)(6), "Biegun, Stephen E" (b)(6), "Bigley, Mark C. EOP/OMB" (b)(6), "Blair, Robert B. EOP/WHO" (b)(6), "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Butterfield, Nicholas W. EOP/WHO" <(b)(6)>, "Campana, Alexandra D. EOP/WHO" (b)(6), "Cetron, Marty (CDC/DDID/NCEZID/DGMQ)" <mzc4@cdc.gov>, "Chafin, Kelly (EOP.GOV)" (b)(6), "Conant, Ann M. EOP/OMB" (b)(6), "Conley, Sean P. CDR USN WHMO/WHMU" (b)(6), "Conrad, Patricia (NIH/NIAID) [E]" (b)(6), "Davis, May M. EOP/WHO" (b)(6), "Ditto, Jessica E. EOP/WHO" (b)(6), "DL Chief of Staff Office" (b)(6), "O'berry, Donna (DOT.GOV)" <donna.o'berry@dot.gov>, "Duffey, Michael P. EOP/OMB" (b)(6), "Eisenberg, John A. EOP/WHO" (b)(6), "Fabina, Lauren C. EOP/NSC" (b)(6), "Fauci, Anthony (NIH/NIAID) [E]" (b)(6), "Ferro, Phil J. EOP/NSC" (b)(6), "Grogan, Joseph J. EOP/WHO" (b)(6), "Hemme, Jake W. EOP/NSC" (b)(6), "Hennessey, Millicent S. EOP/NSC" (b)(6), "Hoelscher, Douglas L. EOP/WHO" (b)(6), "Kan, Derek T. EOP/OMB" (b)(6), "Kenneth. P. rapuano.civ" (b)(6) <Kenneth. P. rapuano.civ (b)(6)>, "Liddell, Christopher P. EOP/WHO" (b)(6), "Miller, Julie L. EOP/OMB" (b)(6), "Mulvaney, Mick M. EOP/WHO" (b)(6), "OS Salesses, Robert" (b)(6), "Pataki, Tim A. EOP/WHO" (b)(6), "Pottinger, Matthew F. EOP/WHO" (b)(6), "Riggs, Charlotte R. EOP/WHO" (b)(6), "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Ruggiero, Anthony J. EOP/NSC" (b)(6), "Scher, Adam A. EOP/OMB" (b)(6), "Shellooe, Ryan P. EOP/NSC" (b)(6), "Sinclair, Michael R. EOP/NSC" (b)(6), "Szabat, Joel (OST)" <Joel.Szabat@dot.gov>, "Troye, Olivia EOP/NSC" (b)(6), "Williams, Michael B. EOP/WHO" (b)(6)

(b)(6)

"Woolfolk, Jon J. EOP/OVP

(b)(6)

**Subject: nCoV WHTF Documents and Deliverables for Review**

Good Afternoon WHTF,

(b)(5)

Please find the following documents attached for consideration by the TF. If amenable to the group, we would propose discussion by the TF at a future date.

**(b)(5)**

Currently, there are no TF calls scheduled Saturday – Monday.

Best Regards,

Phil

Philip J. Ferro, PhD, MS  
Director for Countering Biological Threats  
National Security Council

202.456.1222 (O: (b)(6) cell)

(b)(6)

---

**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 2/24/2020 9:46:46 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: nCoV WHTF Documents and Deliverables for Review

I can work on it. Keagan, can we touch base for a few minutes around 1025 your office?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 9:37 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** RE: nCoV WHTF Documents and Deliverables for Review

Anand – are you working on this, or do you want me to reach out?

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 9:23 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

+Anand

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:20:29 AM EST  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: nCoV WHTF Documents and Deliverables for Review

Can you have folks review and get back to me with their comments? Anand and Keagan, can you coordinate?  
Thx  
S

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:13:13 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

See below. You might want to email him your correct email too.

Sent from my iPhone

Begin forwarded message:

**From:** "Tobias, Lindsay" <Lindsay.Tobias@fda.hhs.gov>  
**Date:** February 24, 2020 at 9:10:34 AM EST  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>

Cc: "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>  
Subject: FW: nCoV WHTF Documents and Deliverables for Review

Looks like AMA may have used wrong email address for SH.

---

**From:** Russ, Wanda <Wanda.Russ@fda.hhs.gov>  
**Date:** February 24, 2020 at 8:48:42 AM EST  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** FW: nCoV WHTF Documents and Deliverables for Review

FYI for Dr. Hahn.

---

**From:** (b)(5) (OS/IOS); (b)(6)@HHS.GOV>  
**Sent:** Saturday, February 15, 2020 2:31 PM  
**To:** Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; FDA Commissioner <Stephen.Hahn@fda.hhs.gov>  
**Cc:** Harrison, Brian (OS) <Brian.Harrison@hhs.gov>  
**Subject:** Fwd: nCoV WHTF Documents and Deliverables for Review

(b)(5)

Thanks.  
AMA

Begin forwarded message:

**From:** "Ferro, Phil J. EOP/NSC" <(b)(6)>  
**Date:** February 14, 2020 at 5:40:34 PM EST  
**To:** (b)(6) (OS/IOS); (b)(6)@HHS.GOV>, AS2KTC (b)(6), "Biegun, Stephen E" (b)(6), "Bigley, Mark C. EOP/OMB" (b)(6), "Blair, Robert B. EOP/WHO" (b)(6), (b)(6), "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Butterfield, Nicholas W. EOP/WHO" (b)(6), "Campana, Alexandra D. EOP/WHO" (b)(6), "Cetron, Marty (CDC/DDID/NCEZID/DGMQ)" <mzc4@cdc.gov>, "Chafin, Kelly (EOP.GOV)" (b)(6), "Conant, Ann M. EOP/OMB" (b)(6), "Conley, Sean P. CDR USN WHMO/WHMU" (b)(6), "Conrad, Patricia (NIH/NIAID) [E]" (b)(6), "Davis, May M. EOP/WHO" (b)(6), "Ditto, Jessica E. EOP/WHO" (b)(6), DL Chief of Staff Office (b)(6), "O'berry, Donna (DOT.GOV)" <donna.o'berry@dot.gov>, "Duffey, Michael P. EOP/OMB" (b)(6), "Eisenberg, John A. EOP/WHO" (b)(6), "Fabina, Lauren C. EOP/NSC" (b)(6), "Fauci, Anthony (NIH/NIAID) [E]" (b)(6), "Ferro, Phil J. EOP/NSC" (b)(6), "Grogan, Joseph J. EOP/WHO" (b)(6), "Hemme, Jake W. EOP/NSC" (b)(6), "Hennessey, Millicent S. EOP/NSC" (b)(6), "Hoelscher, Douglas L. EOP/WHO" (b)(6), "Kan, Derek T. EOP/OMB" (b)(6), "Kenneth.p.rapuano.civ" (b)(6) <Kenneth.p.rapuano.civ> (b)(6), "Liddell, Christopher P. EOP/WHO" (b)(6), "Miller, Julie L. EOP/OMB" (b)(6), "Mulvaney, Mick M. EOP/WHO" (b)(6), "OS Salesses, Robert" (b)(6), "Pataki, Tim A. EOP/WHO" (b)(6), "Pottinger, Matthew F. EOP/WHO" (b)(6), "Riggs,

Charlotte R. EOP/WHO" (b)(6) "Redfield, Robert R. (CDC/OD)" <olx1@cdc.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Ruggiero, Anthony J. EOP/NSC" (b)(6)  
"Scher, Adam A. EOP/OMB" (b)(6), "Shellooe, Ryan P. EOP/NSC"  
(b)(6) "Sinclair, Michael R. EOP/NSC" (b)(6) "Szabat, Joel (OST)" <Joel.Szabat@dot.gov>, "Troye, Olivia EOP/NSC" (b)(6) "Williams, Michael B. EOP/WHO"  
(b)(6) "Woolfolk, Jon J. EOP/OVP" (b)(6)

**Subject: nCoV WHTF Documents and Deliverables for Review**

Good Afternoon WHTF,

(b)(5)

Please find the following documents attached for consideration by the TF. If amenable to the group, we would propose discussion by the TF at a future date.

(b)(5)

Currently, there are no TF calls scheduled Saturday – Monday.

Best Regards,

Phil

Philip J. Ferro, PhD, MS  
Director for Countering Biological Threats  
National Security Council  
202.456.1222 (O) (b)(6) (cell)  
(b)(6)

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/24/2020 11:45:09 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) (OS/IOS) (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccf0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; White, Caroline (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a55bc6c3c0e84313889692f13a8bcf50-HHS-Carolin]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]

**Subject:** AMA call with Daniel O'Day, Gilead Chairman and CEO  
**Attachments:** DOD call request HHS Secr Azar\_February 21 20 FINAL.pdf  
**Location:** 615-F// CALL

**Start:** 2/24/2020 1:10:00 PM  
**End:** 2/24/2020 1:40:00 PM  
**Show Time As:** Busy

**Recurrence:** (none)

YOU will call (b)(6) Mr. O'Day's cellphone.

Backup # (b)(6) Mr. O'Day assistant (b)(6)

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/24/2020 11:45:09 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov] (b)(6) (OS/IOS) (b)(6)@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Hahn, Stephen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; White, Caroline (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a55bc6c3c0e84313889692f13a8bcf50-HHS-Carolin]; Amin, Stacy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Sheehy, Janice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]

**Subject:** AMA call with Daniel O'Day, Gilead Chairman and CEO  
**Attachments:** DOD call request HHS Secr Azar\_February 21 20 FINAL.pdf  
**Location:** 615-F// CALL  
**Start:** 2/24/2020 1:10:00 PM  
**End:** 2/24/2020 1:40:00 PM  
**Show Time As:** Tentative

**Recurrence:** (none)

YOU will call (b)(6) Mr. O'Day's cellphone.

Backup # (b)(6) Mr. O'Day assistant (b)(6)



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/24/2020 1:17:33 PM  
**To:** Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**CC:** Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Urgent request -- remdesivir

Thanks, John

---

**From:** "Farley, John" <John.Farley@fda.hhs.gov>  
**Date:** Monday, February 24, 2020 at 1:09 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>, Stacy Amin <Stacy.Amin@fda.hhs.gov>, "Mair, Michael" <Michael.Mair@fda.hhs.gov>, Denise Hinton <Denise.Hinton@fda.hhs.gov>  
**Cc:** "Raza, Mark" <Mark.Raza@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Urgent request -- remdesivir

We don't have a date yet for the DSMB meeting for the severe patient trial. Will FU with Gilead today.

John Farley  
Office Phone 301-796-4978

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 1:00 PM  
**To:** Farley, John <John.Farley@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: Urgent request -- remdesivir

John,

Do we have any idea of if or when we will hear about: (b)(5)  
Steve

---

**From:** "Farley, John" <John.Farley@fda.hhs.gov>  
**Date:** Monday, February 24, 2020 at 12:21 PM  
**To:** Stacy Amin <Stacy.Amin@fda.hhs.gov>, "Mair, Michael" <Michael.Mair@fda.hhs.gov>, Denise Hinton <Denise.Hinton@fda.hhs.gov>  
**Cc:** "Raza, Mark" <Mark.Raza@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Urgent request -- remdesivir

Providing background. We are reviewing TPs now.

(b)(4)

John Farley  
Office Phone 301-796-4978

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 11:32 AM  
**To:** Farley, John <John.Farley@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Urgent request -- remdesivir  
**Importance:** High

John, Mike –

(b)(5)

\*\*\*\*\*

Stacy Cline Amin  
Chief Counsel  
Food and Drug Administration  
Deputy General Counsel  
Department of Health and Human Services

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/24/2020 1:19:59 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**Subject:** RE: FOR YOUR REVIEW: Updated statement on inspections

Thank you!

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, February 24, 2020 1:18 PM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** Re: FOR YOUR REVIEW: Updated statement on inspections

Thanks, approved from my end  
Steve

---

**From:** Heidi Rebello <Heidi.Rebello@fda.hhs.gov>  
**Date:** Monday, February 24, 2020 at 10:36 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>  
**Cc:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Erika Anderson <Erika.Anderson@fda.hhs.gov>, Carly McWilliams <Carly.McWilliams@fda.hhs.gov>, "Tobias, Lindsay" <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** FOR YOUR REVIEW: Updated statement on inspections

Updated version of the press statement for your review: (b)(5) in coordination with Judy and Carol. Target release is asap. Thank you.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Saturday, February 22, 2020 1:48 PM  
**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

(b)(5)

S

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

**Date:** February 21, 2020 at 8:00:13 PM EST

**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>

**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Actually, 2 more items for your review as soon as you get to them. Tweets are more time sensitive since some need to go over weekend. Statement will go out Monday.

1. COVID-19 inspections statement
2. Tweets for @SteveFDA and main handle

---

**From:** Rebello, Heidi

**Sent:** Friday, February 21, 2020 5:40 PM

**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>

**Subject:** RE: 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

We have a late edition coming your way... The statement on inspections related to outbreak. Will send that along soon; thank you.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>

**Sent:** Friday, February 21, 2020 5:29 PM

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>

**Subject:** 2/21 FRIDAY HOMEWORK - INTERNAL CONFIDENTIAL

Dr. Hahn—

Only homework tonight is to review the below tweets for enhancements to the Purple Book by 9am Monday morning.

“We launched a new, modern version of the Purple Book today to increase transparency about biological products for patients and industry users. [link] [graphic]

The enhancements will meet the needs of a wide range of users – from patients to prescribers, researchers and industry representatives who may need more technical information.

This additional information should help facilitate the acceptance and use of biosimilars, which can increase competition, expanding choices for patients and potentially bring down prices on these important medicines.”

Have a great weekend!

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/24/2020 5:09:00 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: Hold:AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/26/2020 5:30:00 PM  
**End:** 2/26/2020 5:45:00 PM  
**Recurrence:** (none)

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/24/2020 5:27:00 PM  
**Subject:** Dr. Levitt's Update on COVID-19 for 24 February 2020  
**Attachments:** Course of COVID 19 ICU Patients.pdf; Expert WHO Comm. Recs.pdf

Dear All,

Below are the articles I have read today which I believe most pertinent to your missions to contain COVID-19 infection, develop treatment for COVID-19 pneumonitis, and develop a vaccine for the SARS-Cov-2 virus responsible for COVID-19 disease:

**Becker's Hospital Review** reports the White House will seek \$1 Billion from Congress to fight coronavirus in U.S. See: [https://www.beckershospitalreview.com/public-health/white-house-expected-to-seek-1b-to-combat-coronavirus.html?origin=BHRE&utm\\_source=BHRE&utm\\_medium=email&oly\\_enc\\_id=0573J6191345F3O](https://www.beckershospitalreview.com/public-health/white-house-expected-to-seek-1b-to-combat-coronavirus.html?origin=BHRE&utm_source=BHRE&utm_medium=email&oly_enc_id=0573J6191345F3O). This is good news, but \$1 Billion is inadequate. That first Billion should go to an X Prize for a safe human vaccine against this new coronavirus within 3 months in my opinion. A partnership between U.S. and PRC makes this goal attainable. **It's up to President Trump and President Xi now. The loss of \$1 Trillion in value of worldwide stock exchanges today puts the \$1 Billion in perspective.** Three Billion more should be requested from Congress now for this fight. Any credible research effort toward vaccine should receive seed money from the \$3 Billion.

Note that an **error appears in the Becker's ... bullet point list. Only 35% of ICU patients in the PRC report in The Lancet required mechanical ventilation, not two-thirds of those patients.** See pdf attached above.

**The Lancet** has a Comment from WHO's expert committee on the new coronavirus. **Professor Heymann is the lead author.** He gives several recommendation for containing if possible a pandemic. See pdf above. First of all, **every person entering a country needs to be screened for travel to any country with reported COVID-19 cases, fever, cough, fatigue, diarrhea, URI.**

**The Scientist** has today on how **we should use genomic means to determine if PUI (persons under investigation) have COVID-19.** See: [https://www.the-scientist.com/news-opinion/newer-vaccine-technologies-deployed-to-develop-covid-19-shot-67152?utm\\_campaign=TS\\_DAILY%20NEWSLETTER\\_2020&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=83777972&hsenc=p2ANqtz-9lWdXwcXOGltxlvxNck28vb0aXxLizhP0Qvf4WTTEGoasgPXM\\_05mjvV0\\_teGNBwW10kYcKJOPBluncnyBHBButb1\\_9Tg&hsmi=83777972](https://www.the-scientist.com/news-opinion/newer-vaccine-technologies-deployed-to-develop-covid-19-shot-67152?utm_campaign=TS_DAILY%20NEWSLETTER_2020&utm_source=hs_email&utm_medium=email&utm_content=83777972&hsenc=p2ANqtz-9lWdXwcXOGltxlvxNck28vb0aXxLizhP0Qvf4WTTEGoasgPXM_05mjvV0_teGNBwW10kYcKJOPBluncnyBHBButb1_9Tg&hsmi=83777972).

These tests use genomic sequencing, are rapid, are transportable to labs, and some are proven. There is 'a need for speed'. Let's use some of the \$3 Billion for these efforts. The **NYT** has a similar genomics article: <https://www.nytimes.com/2020/02/24/health/genomic-diagnostic-tests.html>

**Vox** contains distressing news (if true) about **only 3 of the lab devices distributed by CDC to 100 public health labs for testing for COVID-19 are working.** See: <https://www.vox.com/2020/2/23/21149327/coronavirus-pandemic-meaning-italy>  
I don't believe the statement. But if true, it can be corrected overnight with technologists on military flights to each lab with a non-working instrument.

RGL, M.D.

*If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at [levittrg@hotmail.com](mailto:levittrg@hotmail.com) and include in the subject line: Unsubscribe.*

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

Sent from Outlook

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/24/2020 6:35:28 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group



---

**CC:** (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]

**Subject:** CIDRAP: Study of 72,000 COVID-19 patients finds 2.3% death rate

<http://www.cidrap.umn.edu/news-perspective/2020/02/study-72000-covid-19-patients-finds-23-death-rate>

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 2/24/2020 8:24:34 PM  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]

Good evening,

First, thank you for lending staff to help us bolster the JIC in the IMG for our COVID-19 outbreak response. Part of the JIC's responsibilities is to be thinking about proactive communications, including how the agency is taking extra precautions to help protect public health.

Today, we issued a press statement on how we are using other tools to monitor the safety of products imported from China in the absence of on-the-ground inspections in China.

One good example of where we are doing this is our expansion of PREDICT, our risk-based import screening tool for surveillance of imported products coming into the U.S. Expanding PREDICT will allow us to focus on areas based on heightened concerns of specific imported products and adjust risk scores as necessary throughout the outbreak.

I understand when this idea was first introduced, centers expressed some concerns whether or not this was a necessary step to take at this time. But, I believe it is important to show we are providing additional steps to ensure the safety of products in lieu of the delayed inspections. I appreciate your staffs' time to work with ORA to accomplish this goal.

Additionally, if you can think of other opportunities for FDA to take additional steps in any of the product areas so we can ensure the public that we are doing everything we can to monitor and protect the products we regulate, please bring them up tomorrow in our 9:15 check in.

I appreciate your commitment to the efforts and look forward to hearing your thoughts.

Steve

Sent from my iPhone

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/24/2020 8:26:43 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: FOR YOUR REVIEW: Draft email to CDs on PREDICT

Well done and thanks  
Sent  
Steve

Sent from my iPhone

On Feb 24, 2020, at 7:15 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

Sir, please review the attached draft email for the center directors. Once you clear, you should send it directly to the center directors from your SH1 account. Here are all the CDs' email addresses that you can cut and paste into your email:

Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Peter Marks <Peter.Marks@fda.hhs.gov>; Jeff Shuren <Jeff.Shuren@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Susan Mayne <Susan.Mayne@fda.hhs.gov>; Mitch Zeller Mitchell.Zeller@fda.hhs.gov; Steve Solomon <Steven.Solomon@fda.hhs.gov>

**(b)(5)**

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 2/24/2020 8:29:51 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Fwd: COVID-19 response

Looks like it just went to Jeff and Steve.

Sent from my iPhone

Begin forwarded message:

**From:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Date:** February 24, 2020 at 8:25:50 PM EST  
**To:** "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Solomon, Steven M" <Steven.Solomon@fda.hhs.gov>  
**Cc:** "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>  
**Subject:** COVID-19 response

Good evening,

First, thank you for lending staff to help us bolster the JIC in the IMG for our COVID-19 outbreak response. Part of the JIC's responsibilities is to be thinking about proactive communications, including how the agency is taking extra precautions to help protect public health.

Today, we issued a press statement on how we are using other tools to monitor the safety of products imported from China in the absence of on-the-ground inspections in China.

One good example of where we are doing this is our expansion of PREDICT, our risk-based import screening tool for surveillance of imported products coming into the U.S. Expanding PREDICT will allow us to focus on areas based on heightened concerns of specific imported products and adjust risk scores as necessary throughout the outbreak.

I understand when this idea was first introduced, centers expressed some concerns whether or not this was a necessary step to take at this time. But, I believe it is important to show we are providing additional steps to ensure the safety of products in lieu of the delayed inspections. I appreciate your staffs' time to work with ORA to accomplish this goal.

Additionally, if you can think of other opportunities for FDA to take additional steps in any of the product areas so we can ensure the public that we are doing everything we can to monitor and protect the products we regulate, please bring them up tomorrow in our 9:15 check in.

I appreciate your commitment to the efforts and look forward to hearing your thoughts.

Steve

Sent from my iPhone

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/24/2020 8:45:26 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** 2/25 Senate Briefing Statement--COVID-19  
**Attachments:** DRAFT SH Senate Update 2.24.20.528\_CDRH (002)CLEARED.docx; Senate HELP Bipar followup questions 2.24.20.pdf; 2020-02-24 LETTER Hawley FDA .pdf

Hi Dr. Hahn-

Attached is a draft statement/update based on our prep today. It's been cleared by the Centers and OCC. We are inclusive in the updates, but obviously you can cut it down if you'd like.

Also, attached are the HELP questions and initial responses. You'll see that we owe them a couple of answers.

Flagging that we still owe Rubio (supply chain) and Scott (inspections) their letter responses. They are in final clearance with ASL, so if they come up, we're very close to providing their responses.

Attaching a letter we received today from Sen. Hawley on the Axios 150 list article. Includes several supply chain questions. More for awareness—we're working on the response.

Sent you some diagnostic test intel from ASL.

Also, Dr. Shuren emailed the below regarding hospital reports of PPE supplies running low

(b)(5)

(b)(5)

I'll continue to send any updates I receive.

Our posture has been that while we have not experienced shortages of PPEs to date, the increased demand and impact of COVID-19 on manufacturing in other countries has put stress on the supply chain. As the outbreak continues we expect to see shortages.

Of note, over time shortages could be seen not only for N95 respirators but for surgical masks and surgical and isolation gowns, as well.

---

**From:** McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]  
**Sent:** 2/24/2020 9:28:20 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**CC:** Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]  
**Subject:** FW: Supp letter  
**Attachments:** Coronavirus Supplemental Request Letter Final.pdf

Letter that went to the Hill

---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/24/2020 10:06:49 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** Fwd: HHS Statement on Coronavirus Supplemental Request

---

**From:** Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>  
**Date:** February 24, 2020 at 10:04:33 PM EST  
**To:** Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>  
**Subject:** HHS Statement on Coronavirus Supplemental Request

Good evening,

Here is a statement from HHS:

“The Administration has been effectively utilizing all available resources to protect the American people from COVID-19. Today, the White House sent a supplemental request to Congress to make \$2.5 billion available for COVID-19 response efforts, including an emergency supplemental appropriation of \$1.25 billion. HHS will also use the Secretary’s transfer authority to provide needed resources to continue the Department’s robust and multi-layered public health preparedness and response efforts – including public health surveillance, epidemiology, laboratory testing, support for state and local governments and other key partners, advanced research and development of new vaccines, therapeutics and diagnostics, advanced manufacturing enhancements, and support for the Strategic National Stockpile.”

Read the letter here: <https://www.whitehouse.gov/wp-content/uploads/2020/02/Coronavirus-Supplemental-Request-Letter-Final.pdf>

All the best,

**Caitlin B. Oakley**  
Deputy Assistant Secretary, National Spokesperson  
Office of the Assistant Secretary for Public Affairs  
U.S. Department of Health and Human Services  
[caitlin.oakley@hhs.gov](mailto:caitlin.oakley@hhs.gov)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/25/2020 2:07:44 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**Subject:** Re: Public health labs press FDA to allow homegrown coronavirus tests

Sent from my iPad

On Feb 24, 2020, at 8:16 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5)

Sent from my iPhone

On Feb 24, 2020, at 8:13 PM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

(b)(5)

---

**From:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>  
**Sent:** Monday, February 24, 2020 7:18 PM  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Cc:** Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>  
**Subject:** FW: Public health labs press FDA to allow homegrown coronavirus tests

This may come up by Schatz or Hirono at tomorrow morning's briefing. Hawaii wants to use Japan's test instead of having to send to CDC for testing.



---

**From:** POLITICO Pro Health Care <politicoemail@politico.com>  
**Sent:** Monday, February 24, 2020 7:16 PM  
**To:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>  
**Subject:** Public health labs press FDA to allow homegrown coronavirus tests

## **Public health labs press FDA to allow homegrown coronavirus tests**

By David Lim

02/24/2020 07:15 PM EST

Public health laboratories urged the FDA on Monday to permit them to create their own tests for the coronavirus, after problems with a diagnostic developed by CDC prevented its widespread rollout.

FDA typically allows "laboratory developed tests" — which are designed, manufactured and used within a single lab — to be used without close regulatory scrutiny. But the agency requires labs to submit such tests for review during health emergencies to prevent harm from false or misleading results from compounding a crisis. The coronavirus does not appear to be an exception.

"No test should be used without being validated," FDA spokesperson Stephanie Caccamo said. "In the context of a public health emergency, false results can lead to significant adverse public health consequences."

The FDA has traditionally shied away from allowing the use of LDTs in emergency situations. In 2016, the agency sent a letter to two Houston hospitals that created an LDT to rapidly detect the Zika virus, expressing concern that the agency had not reviewed the "high-risk" test.

But Association of Public Health Laboratories Executive Director Scott Becker said that the coronavirus requires a different approach. The virus is spreading in multiple countries, and the CDC's efforts to expand testing capability beyond its labs have run into trouble.

Only five state and local public health labs — in California, Nebraska, Illinois, Nevada and Tennessee — have verified the CDC diagnostic for use since the FDA approved it on an emergency basis on Feb. 4, he said.

APHL hopes to work with FDA to develop a policy that allows some labs to market a LDT without submitting it for FDA review, Becker told POLITICO — adding that it doesn't make sense for more than 100 labs to file individual emergency use authority applications.

"We believe a more expeditious route is needed at this time," Becker and Grace Kubin, director of the Laboratory Services Section at the Texas Department of State Health Services, wrote to FDA Commissioner Stephen Hahn on Monday.

"What we're suggesting is that public health labs be viewed as a group to do this," Becker told POLITICO. "It isn't every lab on their own — we would want to do this in a network sort of fashion. We could also enable confirmation at another public health laboratory to ensure confidence."

The letter says that labs could work together towards a standard protocol, purchase reagents and supplies from a common source and recommend a minimum standard approach for validating test results.

Caccamo says that the FDA is working with more than 70 test developers on products for the virus. The agency can complete reviews for such tests in as little as one day, she added — ensuring that it is effective and meets the minimum standards for emergency use.

Some major hospitals are also starting to develop LDTs for coronavirus screening, but are concerned that FDA rules do not permit them to actually start testing patients, according to Michael Mina, associate medical director of molecular diagnostics at Brigham and Women's Hospital.

"We're actually trying to get our test up and running, even though we don't know if we'll be able to use it," Mina said. "I know that Mass General Hospital is also thinking about doing something very similar. I presume all the major academic hospitals are at least considering it."

The American Clinical Laboratory Association, which represents large commercial labs like LabCorp and Quest Diagnostics, declined to comment on whether LDTs should be used to help increase the country's capacity to screen for the coronavirus. Historically, the lab industry trade lobby has maintained LDTs are not medical devices and subject to FDA regulation.

*To view online:*

<https://protect2.fireeye.com/url?k=c0fdd449-9ca9fd62-c0fde576-0cc47a6d17ccb808e97c02f34873&u=https://subscriber.politicopro.com/health-care/article/2020/02/public-health-labs-press-fda-to-allow-homegrown-coronavirus-tests-1884096>

**You received this POLITICO Pro content because your customized settings include: Medical Devices and Products, Infectious Diseases, Public Health. To change your alert settings, please go to <https://protect2.fireeye.com/url?k=13ce68a7-4f9a418c-13ce5998-0cc47a6d17cc6ef0bd4284f83fc8&u=https://subscriber.politicopro.com/settings>.**



This email alert has been sent for the exclusive use of POLITICO Pro subscriber, [laura.pence@hhs.gov](mailto:laura.pence@hhs.gov). Forwarding or reproducing the alert without the express, written permission of POLITICO Pro is a violation of copyright law and the POLITICO Pro subscription agreement.

Copyright © 2020 by POLITICO LLC. To subscribe to Pro, please go to [politicopro.com](http://politicopro.com).

---

This email was sent to [laura.pence@hhs.gov](mailto:laura.pence@hhs.gov) by:  
POLITICO, LLC  
1000 Wilson Blvd.  
Arlington, VA 22209  
USA .

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/25/2020 11:44:39 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Re: COVID-19 response

Went well. Thanks much

---

**From:** Denise Hinton <Denise.Hinton@fda.hhs.gov>  
**Date:** Monday, February 24, 2020 at 10:18 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Cc:** "Rom, Colin" <Colin.Rom@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>  
**Subject:** Re: COVID-19 response

Will do - thank you. Hope the hearing goes well tomorrow.

Denise

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Date:** February 24, 2020 at 8:26:11 PM EST  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
**Subject:** COVID-19 response

Good evening,

First, thank you for lending staff to help us bolster the JIC in the IMG for our COVID-19 outbreak response. Part of the JIC's responsibilities is to be thinking about proactive communications, including how the agency is taking extra precautions to help protect public health.

Today, we issued a press statement on how we are using other tools to monitor the safety of products imported from China in the absence of on-the-ground inspections in China.

One good example of where we are doing this is our expansion of PREDICT, our risk-based import screening tool for surveillance of imported products coming into the U.S. Expanding PREDICT will allow us to focus on areas based on heightened concerns of specific imported products and adjust risk scores as necessary throughout the outbreak.

I understand when this idea was first introduced, centers expressed some concerns whether or not this was a necessary step to take at this time. But, I believe it is important to show we are providing additional steps to ensure the safety of products in lieu of the delayed inspections. I appreciate your staffs' time to work with ORA to accomplish this goal.

Additionally, if you can think of other opportunities for FDA to take additional steps in any of the product areas so we can ensure the public that we are doing everything we can to monitor and protect the products we regulate, please bring them up tomorrow in our 9:15 check in.

I appreciate your commitment to the efforts and look forward to hearing your thoughts.

Steve

Sent from my iPhone

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/25/2020 12:18:24 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS) [AMA2@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddd-HHS-Kyle.Ze]; Hahn, Stephen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Lukens IV, Mel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaa0ae6a04b943ec9d926f56f4c50b50-HHS-Mel.Luk]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Olivarria, Frank (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]

**Subject:** AMA coronavirus update with members of Press conference  
**Location:** HHS Studio Green Room

---

**Start:** 2/25/2020 2:45:00 PM  
**End:** 2/25/2020 3:00:00 PM  
**Show Time As:** Tentative

**Recurrence:** (none)

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/25/2020 12:53:29 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

---

CC: [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Olivarria, Frank  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Measer, Gregory  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]  
Subject: Availability: Cleared FDA talking points for FDA IMG and AEG use

Dear COVID-19 AEG,

This week's final OCC-cleared talking points are now available in the IMG SharePoint → [Talking Points folder](#).

Each week, JIC will update the talking points, and replace with a **new weekly version on Mondays**. (You may want to bookmark the folder and reference this version, to be sure you are always working from the latest copy.) When you see the updated talking points for review each week from your center/office JIC rep, we'll flag what has changed for easy reference.

Please do not edit the cleared talking points list. If you need to request a change, please work with a JIC member to do this—we have a process in place.

Many thx for everyone's' help in getting this document / process together, in particular April Finnen in OCET, Stephanie Caccomo in OMA, and to the OL team, for providing many of the cleared source documents for this list.

If you do not have access to the document on sharepoint let me know.



-m

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 2/25/2020 6:13:59 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Navarro called Dr. Hahn last week right before COVID check in and asked that we put together proposals for what we would like to see in an advanced manufacturing EO but didn't give a timeline and his team has been reaching out like you and I had discussed last week not recognizing that this takes more than a few days to put together

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Tuesday, February 25, 2020 6:09 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** RE: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Not really sure what else we are waiting on. Can you share the ask or CDRH list?

(b)(5)

(b)(5)

don't know what the asks are though, so tough to weigh in.

---

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Sent:** Tuesday, February 25, 2020 6:02 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Re: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

We haven't received the list of line item proposals from CDER or CBER yet that Navarro has been asking for also. But I have asked for those ASAP. CDRH has theirs put together but wanted them to all go together so Navarro doesn't get one set and just try to move with something incomplete.

What are thoughts?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** February 25, 2020 at 5:51:47 PM EST  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** FW: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Let me know how you all want to handle this?

---

**From:** Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>  
**Sent:** Tuesday, February 25, 2020 4:44 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>

**Subject:** Reply to Dr. Peter Navarro regarding Supply Situation for “List of Essential Medications for Severe CVD Infection”

Good Afternoon Keagan,

I am attaching the CDER-cleared response to Dr. Navarro’s request for information on the supply of products on the “List of Essential Medications for Severe CVD Infection.” I’m also attaching a suggested cover memo. Please let me know if you have any questions or need additional information.

Thank you,  
Jessica

Jessica Bernstein, MPH  
Office of Executive Programs, CDER  
Office phone: 240-402-0524

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/25/2020 6:33:12 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Maj]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Update on Coronavirus

**Location:** Oval Office

**Start:** 2/26/2020 6:00:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/25/2020 6:33:12 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6) HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenithia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenith]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Update on Coronavirus

**Location:** Oval Office

**Start:** 2/26/2020 6:00:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/25/2020 6:33:12 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS (b)(6)@HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Maj]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Task Force Briefing

**Location:** Oval Office

**Start:** 2/26/2020 6:00:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

This email is to inform you that a Coronavirus Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.

DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:00 PM (30 min)

LOCATION: Roosevelt Room

EVENT FORMAT/PROGRAM: Meeting

PRESS: Closed

ADMINISTRATION PARTICIPANTS:

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

INTERNAL PARTICIPANTS:

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/25/2020 6:46:38 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FW: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"  
**Attachments:** Supply Situation for Essential Medications for Severe CVD\_to KL\_02252020.docx; WH List of Essential Medications\_FDA cover memo\_to KL\_02252020.docx

Could you send for us along the lines of?

(b)(5)

Thanks

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Tuesday, February 25, 2020 at 5:51 PM  
**To:** "Rom, Colin" <Colin.Rom@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** FW: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Let me know how you all want to handle this?

---

**From:** Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>  
**Sent:** Tuesday, February 25, 2020 4:44 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>  
**Subject:** Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Good Afternoon Keagan,

I am attaching the CDER-cleared response to Dr. Navarro's request for information on the supply of products on the "List of Essential Medications for Severe CVD Infection." I'm also attaching a suggested cover memo. Please let me know if you have any questions or need additional information.

Thank you,  
Jessica

Jessica Bernstein, MPH  
Office of Executive Programs, CDER  
Office phone: 240-402-0524



---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/25/2020 8:20:02 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** E&C Qs

A few E&C questions we here may be coming your way and some suggested answers.

**(b)(5)**

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/25/2020 9:33:03 PM  
**Subject:** Dr. Levitt's Update on COVID-19 for 25 February 2020/How Dr. Starkloff stopped Influenza in Saint Louis in 1918

Dear All,

Here are most pertinent articles in journals or online today re: COVID-19 in my opinion:

**SHEA** has a concise and excellent summary of the past week's events and journal articles at: [https://contentsharing.net/actions/email\\_web\\_version.cfm?ep=N8\\_79D-p--sUGwsLnJINQYJ2WCRJVBC5Ov0edxZzIYtLxjTtaJ8jh90Cm4JJ9\\_YQ1tb6p9yCPY-WpdDoQgz2R9tYQchtFJ-1arEW7b6NJFgHLMuzZEUgPcNDLwdeb9IG](https://contentsharing.net/actions/email_web_version.cfm?ep=N8_79D-p--sUGwsLnJINQYJ2WCRJVBC5Ov0edxZzIYtLxjTtaJ8jh90Cm4JJ9_YQ1tb6p9yCPY-WpdDoQgz2R9tYQchtFJ-1arEW7b6NJFgHLMuzZEUgPcNDLwdeb9IG)

This SHEA summary under 'Federal...' **lists the CDC website to obtain daily CDC updates to your email address.**

**CDC Early Release of MMWR on Public Health Measures** taken by U.S. to contain spread of SARS-CoV-2 in U.S. was released this

morning: [https://www.cdc.gov/mmwr/volumes/69/wr/mm6908e1.htm?s\\_cid=mm6908e1\\_e&deliveryName=USCDC\\_921-DM20815](https://www.cdc.gov/mmwr/volumes/69/wr/mm6908e1.htm?s_cid=mm6908e1_e&deliveryName=USCDC_921-DM20815)

The author, Dr. Jerigan at CDC, is transparent and complete in his Release. He writes that the spread of virus to U.S. can be slowed but not fully stopped; that all flights from PRC are being diverted to 11 airports in U.S. where enhanced screening is taking place (positive tests range from 3- 14%); that the CDC's RT-PCR instruments have a faulty component and will be repaired and supported by serologic CDC tests which measure IgG, A, M antibody response to the virus. Jerigan raises the possibility of school closures, meetings cancelled, working from home if the virus spreads in the U.S. **Note that the mortality rate for this novel coronavirus is 2.3% to date; the mortality rate for Influenza is 0.1%.**

**CGTN** reports that **PRC has a serologic test for the coronavirus which produces an answer in 15**

**minutes:** [https://news.cgtn.com/news/2020-02-15/China-develops-COVID-19-detection-kit-that-delivers-results-in-15-min--O6aPGKuzGo/index.html?utm\\_source=STAT+Newsletters&utm\\_campaign=c06894f8a3-stat\\_china\\_COPY\\_01&utm\\_medium=email&utm\\_term=0\\_8cab1d7961-c06894f8a3-131085113](https://news.cgtn.com/news/2020-02-15/China-develops-COVID-19-detection-kit-that-delivers-results-in-15-min--O6aPGKuzGo/index.html?utm_source=STAT+Newsletters&utm_campaign=c06894f8a3-stat_china_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-c06894f8a3-131085113)

**STAT Morning Report** quotes CDC officials other than Jerigan that agree this novel coronavirus may have serious impact on the U.S. economy, schools, meeting

places. See: [https://www.statnews.com/2020/02/25/cdc-expects-community-spread-of-coronavirus-as-top-official-warns-disruptions-could-be-severe/?utm\\_source=STAT+Newsletters&utm\\_campaign=01f418b1d0-breaking\\_COPY\\_01&utm\\_medium=email&utm\\_term=0\\_8cab1d7961-01f418b1d0-131085113](https://www.statnews.com/2020/02/25/cdc-expects-community-spread-of-coronavirus-as-top-official-warns-disruptions-could-be-severe/?utm_source=STAT+Newsletters&utm_campaign=01f418b1d0-breaking_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-01f418b1d0-131085113)

**Nature Biotechnology** details **all of the RT-PCR kits that do work for detecting the novel coronavirus and the nucleic acid identification kits** as well: [https://www.nature.com/articles/d41587-020-00002-2?utm\\_source=Nature+Briefing&utm\\_campaign=c3e5323668-briefing-dy-20200225&utm\\_medium=email&utm\\_term=0\\_c9dfd39373-c3e5323668-42078415](https://www.nature.com/articles/d41587-020-00002-2?utm_source=Nature+Briefing&utm_campaign=c3e5323668-briefing-dy-20200225&utm_medium=email&utm_term=0_c9dfd39373-c3e5323668-42078415)

Some labs can run 10,000 tests/day.

**The Scientist** has an article by Katarina Zimmer (my favorite science writer) which specifies **which seniors die most frequently from the novel coronavirus: heart disease 10.5%, diabetics 7.5%, cancer, hypertension, or COPD 6%.** The virus may affect men more than women. This virus may be more severe than other coronaviruses (causing common colds) because it attaches to the ACE-2 receptor in the respiratory lining of

upper and **lower airways**. See: [https://www.the-scientist.com/news-opinion/why-some-covid-19-cases-are-worse-than-others-67160?utm\\_campaign=TS\\_DAILY%20NEWSLETTER\\_2020&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=83842644&hsenc=p2ANqtz-8-pVrL8fZlpC5V5FA3nVb\\_BOPV3nNTNay7ityZXCyDWc00q1NPEec79skjHmFvL5i7XopMTE0qJ7g9s8sM0F9E7H1QDQ&hsmi=83842644](https://www.the-scientist.com/news-opinion/why-some-covid-19-cases-are-worse-than-others-67160?utm_campaign=TS_DAILY%20NEWSLETTER_2020&utm_source=hs_email&utm_medium=email&utm_content=83842644&hsenc=p2ANqtz-8-pVrL8fZlpC5V5FA3nVb_BOPV3nNTNay7ityZXCyDWc00q1NPEec79skjHmFvL5i7XopMTE0qJ7g9s8sM0F9E7H1QDQ&hsmi=83842644).

**NIH** has begun a trial to test the efficacy/safety of **Remdesivir** against this novel coronavirus. This anti-viral drug has worked somewhat against MERS and SARS. Patients will be those at University of Nebraska who were repatriated from Asia. See: <https://www.nih.gov/news-events/news-releases/nih-clinical-trial-remdesivir-treat-covid-19-begins>

All sorts of anti-virals are undergoing trials in PRC according to the WHO listing of world clinical trials.

For readers interested in **how a health commissioner in Saint Louis, Dr. Max. C. Starkloff, saved thousands of lives in the 1918 Influenza epidemic in my city, read the following 1918 archival**

**report:** <https://www.influenzaarchive.org/cities/city-stlouis.html#>.

Starkloff followed the epidemic news in Boston and applied measures in Saint Louis to stop an epidemic here. Measures included isolating troops from the public, closing schools and churches and taverns and meetings, daytime business hours only, no children in theatres, building hospitals, tents for patients, etc. The archive is an example of what should be done if an epidemic of the novel coronavirus should begin in the U.S.

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/26/2020 7:52:25 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS (b)(6)@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenithia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenithia]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Task Force Briefing

**Location:** Roosevelt Room

**Start:** 2/26/2020 6:00:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

This email is to inform you that a Coronavirus Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.

DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:00 PM (30 min)

LOCATION: Roosevelt Room

EVENT FORMAT/PROGRAM: Meeting

PRESS: Closed

ADMINISTRATION PARTICIPANTS:

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

INTERNAL PARTICIPANTS:

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/26/2020 8:35:56 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) (OS/IOS); (b)(6) @HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Task Force Briefing

**Location:** Oval Office

**Start:** 2/26/2020 6:00:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

Hi all,

Please see the UPDATED time and location for the Coronavirus Briefing today at 6:15 PM.

Thank you,  
Kimberly

This email is to inform you that a Coronavirus Taskforce Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.

DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:15 PM (15 min)

LOCATION: Oval Office

EVENT FORMAT/PROGRAM: Meeting

PRESS: Closed

ADMINISTRATION PARTICIPANTS:

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Robert Redfield, Director, Centers for Disease Control Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

INTERNAL PARTICIPANTS:

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Jared Kushner, Assistant to the President and Senior Advisor Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Larry Kudlow, Assistant to the President and Director of the National Economic Council Peter Navarro, Assistant to the President for Trade and Manufacturing Policy Kellyanne Conway, Assistant to the President and Counselor to the President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Eric Ueland, Assistant to the President and Director of Legislative Affairs Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/26/2020 8:35:56 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6) @HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Task Force Briefing

**Location:** Oval Office

**Start:** 2/26/2020 6:15:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

Hi all,

Please see the UPDATED time and location for the Coronavirus Briefing today at 6:15 PM.

Thank you,  
Kimberly

This email is to inform you that a Coronavirus Taskforce Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.



DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:15 PM (15 min)

LOCATION: oval Office

EVENT FORMAT/PROGRAM: Meeting

PRESS: Closed

ADMINISTRATION PARTICIPANTS:

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Robert Redfield, Director, Centers for Disease Control Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

INTERNAL PARTICIPANTS:

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Jared Kushner, Assistant to the President and Senior Advisor Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Larry Kudlow, Assistant to the President and Director of the National Economic Council Peter Navarro, Assistant to the President for Trade and Manufacturing Policy Kellyanne Conway, Assistant to the President and Counselor to the President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Eric Ueland, Assistant to the President and Director of Legislative Affairs Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/26/2020 8:35:56 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; (b)(6) OS/IOS; (b)(6) @HHS.GOV; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Task Force Briefing

**Location:** Oval Office

**Start:** 2/26/2020 6:15:00 PM

**End:** 2/26/2020 6:45:00 PM

**Show Time As:** Tentative

**Recurrence:** (none)

Hi all,

Please see the UPDATED time and location for the Coronavirus Briefing today at 6:15 PM.

Thank you,  
Kimberly

This email is to inform you that a Coronavirus Taskforce Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.

DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:15 PM (15 min)

LOCATION: oval Office

EVENT FORMAT/PROGRAM: Meeting

PRESS: Closed

ADMINISTRATION PARTICIPANTS:

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Robert Redfield, Director, Centers for Disease Control Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

INTERNAL PARTICIPANTS:

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Jared Kushner, Assistant to the President and Senior Advisor Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Larry Kudlow, Assistant to the President and Director of the National Economic Council Peter Navarro, Assistant to the President for Trade and Manufacturing Policy Kellyanne Conway, Assistant to the President and Counselor to the President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Eric Ueland, Assistant to the President and Director of Legislative Affairs Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/26/2020 11:09:58 AM  
**To:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: maj members asking questions at COVID sidecar

Thx

---

**From:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Date:** February 26, 2020 at 11:09:27 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: maj members asking questions at COVID sidecar

Can chat more at leg check in but FYI

---

**From:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>  
**Date:** February 26, 2020 at 11:07:53 AM EST  
**To:** LaMontagne, Karen A (NIH) <karen.lamontagne@nih.gov>, Brand, Anstice M (CDC) <atb6@cdc.gov>, Bigham, Jane E (CDC) <vsy0@cdc.gov>, Tourk, Nancy R (CDC) <wxk8@cdc.gov>, Greaser, Jennifer L (CDC) <cbx5@cdc.gov>, Oxner, Julie (OS) <Julie.Oxner@hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Cc:** Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>, Morse, Sara N (OS) <Sara.Morse@hhs.gov>  
**Subject:** maj members asking questions at COVID sidecar

Eshoo  
DeGette  
Ruiz  
Schakowsky  
Dingell

---

**From:** SH1@fda.hhs.gov [SH1@fda.hhs.gov]  
**Sent:** 2/26/2020 11:10:07 AM  
**To:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: maj members asking questions at COVID sidecar

Thx

---

**From:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Date:** February 26, 2020 at 11:09:27 AM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Fwd: maj members asking questions at COVID sidecar

---

**From:** DLGDESK (HHS/ASPR/OPP) (b)(6)  
**Sent:** 2/26/2020 12:07:12 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Stannard, Paula (OS); Agnew, Ann (OS); Trueman, Laura (OS); Kadlec, Robert P (OS); Rowell, Scott (OS); Moughalian, Jen C (OS); Arbes, Sarah C (OS); Murphy, Ryan (OS); Destro, Brenda (OS); Tobias, Constance (OS); Giroir, Brett (OS); Severino, Roger (OS); Grigsby, Garrett G (OS); Charrow, Robert (OS); Grimm, Christi A (OIG); Griswold, Nancy J (OS); Johnson, Lynn (ACF); Robertson, Lance (ACL); Khanna, Gopal (AHRQ); Redfield, Robert R (CDC); Verma, Seema (CMS); Hahn, Stephen; Engels, Thomas J (HRSA); Weahkee, Michael (IHS); Collins, Francis S (NIH); McCance-Katz, Elinore (SAMHSA); Shuy, Bryan (OS); Yeskey, Kevin (OS); Bright, Rick (OS); Phillips, Sally (OS); Smith, Matthew (OS); Greene, Jonathan (OS); Waters, Cicely (OS); Imbriale, Samuel (OS); Cooper, Kevin (OS); Falcon, Jessica (OS); DeBord, Kristin (OS); Austin, Meredith (uscg.mil); Wolf, Laura K (OS); Perdue, Christopher (OS); Herrmann, John (OS); Johnson, Robert (OS); Wong, Diana (OS); Vineyard, Michael (OS); OS Secretarys Operations Center; OS Salesses, Robert; Terry.m.rauch.civ@mail.mil; Caneva, Duane (DHS.GOV); OS Bibo, David; Kim, Paul (VA.GOV); Philip.j.ferro@nsc.eop.gov; Roman-Stolte, Claudia (OS); Fucci, Michael (OS); Dodgen, Daniel (OS); Ford-Barnes, Arwenithia (OS)

**Subject:** Save-the-Date: Disaster Leadership Group (DLG) COVID-19 Response Coordination  
**Location:** ASPR Main Conference Room, 638G, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201 | Conference Line: TBA

**Start:** 2/28/2020 10:45:00 AM  
**End:** 2/28/2020 11:45:00 AM  
**Show Time As:** Tentative

Dear Disaster Leadership Group (DLG) Members:

The Assistant Secretary for Preparedness and Response (ASPR) will convene a DLG meeting on February 28, 2020 from 10:45 AM to 11:45 AM.

### **DLG Intent**

The purpose of this DLG is to gather HHS and interagency senior leaders to provide Departmental updates on COVID-19 activities and discuss coordination and mitigation strategies for current and future activities.

### **Meeting Logistics**

Due to the confidential nature of the information that may be discussed during this forum, we ask that you **DO NOT forward** this meeting invitation to other colleagues. **Please note:** only those listed on the distribution list will be allowed to join the call. Please direct any requests to modify the distribution list for this DLG meeting to the DLGDESK resource mailbox at: (b)(6) Requests to modify the distribution list **must be made by COB Thursday, February 27.**

### **Joining Remotely**

A conference line will be made available for participants to join the meeting remotely. **Please join the conference line at least 15 minutes prior to the start of the meeting.**

**Conference Line: TBD**

**Participant Code: TBD**

**PowerPoint Presentation: TBD**

This session will be held in the ASPR Main Conference Room, 638G, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. The meeting agenda and conference line information will be sent as an update to this calendar invitation.

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

**HEALTH AND HUMAN SERVICES (DHHS)** | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | [www.phe.gov](http://www.phe.gov)

**From:** DLGDESK (HHS/ASPR/OPP) (b)(6)  
**Sent:** 2/26/2020 12:07:32 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Hahn, Stephen (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Engels, Thomas J (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; Collins, Francis S (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; McCance-Katz, Elinore (SHY) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffc7b280b7bc-HHS-Samuel.]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Falcon, Jessica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; OS Salesses, Robert [Robert.g.salesses.civ@mail.mil]; Terry.m.rauch.civ@mail.mil; Caneva, Duane (DHS.GOV) [duane.caneva@hq.dhs.gov]; OS Bibo, David [David.Bibo@fema.dhs.gov]; Kim, Paul (VA.GOV) [paul.kim@va.gov]; Philip.j.ferro@nsc.eop.gov; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Dodgen, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

**Subject:** Save-the-Date: Disaster Leadership Group (DLG) COVID-19 Response Coordination  
**Location:** ASPR Main Conference Room, 638G, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201 | Conference Line: TBA

**Start:** 2/28/2020 10:45:00 AM  
**End:** 2/28/2020 11:45:00 AM  
**Show Time As:** Busy

**Recurrence:** (none)

Dear Disaster Leadership Group (DLG) Members:

The Assistant Secretary for Preparedness and Response (ASPR) will convene a DLG meeting on February 28, 2020 from 10:45 AM to 11:45 AM.

### **DLG Intent**

The purpose of this DLG is to gather HHS and interagency senior leaders to provide Departmental updates on COVID-19 activities and discuss coordination and mitigation strategies for current and future activities.

### **Meeting Logistics**

Due to the confidential nature of the information that may be discussed during this forum, we ask that you **DO NOT forward** this meeting invitation to other colleagues. **Please note:** only those listed on the distribution list will be allowed to join the call. Please direct any requests to modify the distribution list for this DLG meeting to the DLGDESK resource mailbox at: **(b)(6)**  
Requests to modify the distribution list **must be made by COB Thursday, February 27.**

### **Joining Remotely**

A conference line will be made available for participants to join the meeting remotely. **Please join the conference line at least 15 minutes prior to the start of the meeting.**

**Conference Line: TBD**

**Participant Code: TBD**

**PowerPoint Presentation: TBD**

This session will be held in the ASPR Main Conference Room, 638G, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. The meeting agenda and conference line information will be sent as an update to this calendar invitation.

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | www.phe.gov

**From:** DLGDESK (HHS/ASPR/OPP) (b)(6)  
**Sent:** 2/26/2020 12:07:32 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS)

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Phillips, Sally (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Smith, Matthew (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Waters, Cicely (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Imbriale, Samuel (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Cooper, Kevin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Falcon, Jessica (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]; DeBord, Kristin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; OS Salesses, Robert [Robert.g.salesses.civ@mail.mil]; Terry.m.rauch.civ@mail.mil; Caneva, Duane (DHS.GOV) [duane.caneva@hq.dhs.gov]; OS Bibo, David [David.Bibo@fema.dhs.gov]; Kim, Paul (VA.GOV) [paul.kim@va.gov]; Philip.j.ferro@nsc.eop.gov; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Fucci, Michael (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Dodgen, Daniel (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

**Subject:** Save-the-Date: Disaster Leadership Group (DLG) COVID-19 Response Coordination  
**Location:** ASPR Main Conference Room, 638G, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201 | Conference Line: TBA

**Start:** 2/28/2020 10:45:00 AM  
**End:** 2/28/2020 11:45:00 AM  
**Show Time As:** Tentative

**Recurrence:** (none)

Dear Disaster Leadership Group (DLG) Members:

The Assistant Secretary for Preparedness and Response (ASPR) will convene a DLG meeting on February 28, 2020 from 10:45 AM to 11:45 AM.

## **DLG Intent**

The purpose of this DLG is to gather HHS and interagency senior leaders to provide Departmental updates on COVID-19 activities and discuss coordination and mitigation strategies for current and future activities.

## **Meeting Logistics**

Due to the confidential nature of the information that may be discussed during this forum, we ask that you **DO NOT forward** this meeting invitation to other colleagues. **Please note:** only those listed on the distribution list will be allowed to join the call. Please direct any requests to modify the distribution list for this DLG meeting to the DLGDESK resource mailbox at **(b)(6)**. Requests to modify the distribution list **must be made by COB Thursday, February 27.**

## **Joining Remotely**

A conference line will be made available for participants to join the meeting remotely. **Please join the conference line at least 15 minutes prior to the start of the meeting.**

**Conference Line: TBD**

**Participant Code: TBD**

**PowerPoint Presentation: TBD**

This session will be held in the ASPR Main Conference Room, 638G, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. The meeting agenda and conference line information will be sent as an update to this calendar invitation.

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | [www.phe.gov](http://www.phe.gov)

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/26/2020 1:40:38 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS) [AMA2@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Callaghan-Arguelles, Christine B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d29f1f4115f4fe4869917e831b7410f-HHS-Christi]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]

**Subject:** AMA WH Task Force Briefing

**Location:** Cabinet Room

**Start:** 2/26/2020 6:00:00 PM

**End:** 2/26/2020 6:30:00 PM

**Show Time As:** Busy

**Recurrence:** (none)

Hi all,

Please see the UPDATED time and location for the Coronavirus Briefing today at 6:15 PM.

Thank you,  
Kimberly

This email is to inform you that a Coronavirus Taskforce Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.

DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:15 PM (15 min)

LOCATION: oval Office

EVENT FORMAT/PROGRAM: Meeting

PRESS: Closed

ADMINISTRATION PARTICIPANTS:

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Robert Redfield, Director, Centers for Disease Control Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

INTERNAL PARTICIPANTS:

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Jared Kushner, Assistant to the President and Senior Advisor Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Larry Kudlow, Assistant to the President and Director of the National Economic Council Peter Navarro, Assistant to the President for Trade and Manufacturing Policy Kellyanne Conway, Assistant to the President and Counselor to the President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Eric Ueland, Assistant to the President and Director of Legislative Affairs Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget

---

**From:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Sent:** 2/26/2020 1:40:38 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS); Apple, Matthew (OS); Callaghan-Arguelles, Christine B (OS); Harrison, Brian (OS); Mango, Paul (OS); Puesan, Cesar (OS); Stecker, Judy (OS); Tignor, Beth (OS); Redfield, Robert R (CDC); Williams, Teresa (CDC); Gershman, Lynn E (CDC); Schuchat, Anne (CDC); Kadlec, Robert P (OS); Ford-Barnes, Arwenchia (OS); Olivarria, Frank; Sheehy, Janice; Hahn, Stephen; Conrad, Patricia L (NIH); Fauci, Anthony S (NIH)  
**Subject:** AMA WH Task Force Briefing  
**Location:** Oval Office  
**Start:** 2/26/2020 6:00:00 PM  
**End:** 2/26/2020 6:30:00 PM  
**Show Time As:** Busy

**Recurrence:** (none)

Hi all,

Please see the UPDATED time and location for the Coronavirus Briefing today at 6:15 PM.

Thank you,  
Kimberly

This email is to inform you that a Coronavirus Taskforce Briefing has been APPROVED and added to the President's schedule. Information regarding your event is below.

DATE/TIME/LENGTH OF PARTICIPATION: Wednesday, February 26, 2020 at 6:15 PM (15 min)

LOCATION: oval office

EVENT FORMAT/PROGRAM: Meeting

PRESS: closed

**ADMINISTRATION PARTICIPANTS:**

Secretary Alex Azar, Department of Health and Human Services Deputy Secretary Stephen Biegun, Department of State Acting Deputy Secretary Ken Cuccinelli, Department of Homeland Security Acting Under Secretary for Policy Joel Szabat, Department of Transportation Dr. Stephen Hahn, Commissioner, Food and Drug Administration Dr. Robert Redfield, Director, Centers for Disease Control Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases Dr. Robert Kadlec, Assistant Secretary for Preparedness and Response, Department of Health and Human Services

**INTERNAL PARTICIPANTS:**

The Vice President

Mick Mulvaney, Acting White House Chief of Staff Jared Kushner, Assistant to the President and Senior Advisor Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination Marc Short, Assistant to the President and Chief of Staff to the Vice President LTG Keith Kellogg, Assistant to the President and National Security Advisor to the Vice President Larry Kudlow, Assistant to the President and Director of the National Economic Council Peter Navarro, Assistant to the President for Trade and Manufacturing Policy Kellyanne Conway, Assistant to the President and Counselor to the President Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council Eric Ueland, Assistant to the President and Director of Legislative Affairs Matthew Pottinger, Assistant to the President and Deputy National Security Advisor Jessica Ditto, Deputy Assistant to the President and Deputy Director of Communications Derek Kan, Executive Associate Director, Office of Management and Budget



---

**From:** Dareshori, Zack (HHS/IOS) [Zachary.Dareshori@hhs.gov]  
**Sent:** 2/26/2020 6:24:37 PM  
**To:** Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcb164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: FDA Heads Up for HHS NN - 2/27/20

Thank you, very much appreciated. No worries at all!

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
**Sent:** Wednesday, February 26, 2020 5:57 PM  
**To:** Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas (FDA/OC) <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara (FDA/OC) <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: FDA Heads Up for HHS NN - 2/27/20

Yes, will do and very sorry!

---

**From:** Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>

**Date:** February 26, 2020 at 5:51:22 PM EST

**To:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Mango, Paul (OS) <Paul.Mango@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Beshara, Nicholas <Nicholas.Beshara@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Beardsley, Sara <Sara.Beardsley@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** RE: FDA Heads Up for HHS NN - 2/27/20

Thanks FDA. Would it be possible to try and send this by the 3pm deadline going forward? We have been having issues lately with getting the night note compiled on time. Maybe you can send what you have at 3pm and if anything additional comes up we can always put together a supplemental update. I am more than happy to discuss with any of you if helpful. Thanks very much

---

**From:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

**Sent:** Wednesday, February 26, 2020 4:57 PM

**To:** Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

**Cc:** Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>; Beshara, Nicholas (FDA/OC) <Nicholas.Beshara@fda.hhs.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>; Beardsley, Sara (FDA/OC) <Sara.Beardsley@fda.hhs.gov>; Anderson, Erika (FDA/OC) <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>

**Subject:** FDA Heads Up for HHS NN - 2/27/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/27/20:

- **FDA to continue to provide updates on COVID-19 response effort**

Tomorrow and this week, FDA is expected to continue to communicate on its work in response to the novel coronavirus outbreak (COVID-19).

- **FDA responds to FOIA on sodium**

In response to a FOIA request, FDA is releasing a 2013 HHS analysis of the value of a national reduction in dietary sodium from restaurant and processed foods to the Center for Science in the Public Interest. The analysis examines benefits and concludes that reducing dietary sodium would reduce blood pressure and extend life and quality-adjusted life years and would reduce medical expenditures.

- **FDA to approve first generic of Daraprim tablets (confidential)**

Possibly tomorrow or Friday, FDA is expected to approve the first generic of Daraprim (pyrimethamine) tablets for the treatment of toxoplasmosis (an infection caused by the parasite *Toxoplasma gondii*) when used with a sulfonamide (a group of medicines used to treat bacterial infections). Daraprim was originally approved in 1953.

- **FDA to warn against certain devices making false claims about CPAP machines**

Tomorrow, FDA will issue a safety communication about devices claiming to clean CPAP machines using ozone gas or UV light that have not been FDA authorized.

- **FDA to highlight important role of PHS Commissioned Corps in COVID-19 response**

Tomorrow or Friday, FDA will highlight the critical work being done by FDA Commissioned Corps Officers on the frontline of the COVID-19 response.

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/26/2020 9:27:46 PM  
**Subject:** Dr. Levitt's Update on COVID-19 for 26 Feb 2020  
**Attachments:** Wuhan CoV NEJM Editorial.pdf

Dear All,

Here are brief summaries of the journal articles and online articles I have read today re: SARS-CoV-2 and/or COVID-19:

**President Trump** held a Press Briefing in the WH this evening and placed VP Pence in charge of his response to coronavirus. See:

<https://www.c-span.org/video/?469747-1/president-trump-announces-vice-president-pence-charge-coronavirus-response>

for the complete text of the news conference by CSPAN. The President stated that the risk of the virus spreading throughout the U.S. is small; that a vaccine against the virus is well on its way in development, and that infected patients are getting better. CDC officials and Dr. Tom Frieden, former head of CDC have said otherwise.

**NEJM** online tonight has a Perspective on the novel coronavirus. See Wuhan pdf attached above. The perspective is well written and puts this zoonotic outbreak in historical perspective. For me, the most important statement in the perspective was:

*"It took the genome of the human species 8 million years to evolve by 1%. Many animal RNA viruses can evolve by more than 1% in a matter of days. It is not difficult to understand why we increasingly see the emergence of zoonotic viruses."*

All a virus does is replicate using another host for energy to replicate. As it replicates, it makes errors in replication and may become more transmissible or deadly to humans. That is why experts are calling for more help from Congress in terms of money to try for containment, contact isolation, vaccine, and treatment of this novel coronavirus.

**Washington Post** recently reported that the number of airports screening for coronavirus had been increased to 20 airports, including Miami International Airport. Flights from Wuhan, Hubei, PRC are directed to 5 of these 20 airports for enhanced screening for coronavirus. See:

<https://www.washingtonpost.com/transportation/2020/01/30/us-health-officials-expand-screening-new-coronavirus-20-airports/>

Spring Break is rapidly approaching. Thousands of students will descend upon Florida in March to enjoy the sun and sea. **In my opinion, all airplane passengers, all cruise passengers, and all non-Florida license plate vehicles crossing into Florida during March should have passengers screened for fever, cough, diarrhea, and URI as well as travel to countries with COVID-19 to prevent an epidemic in Florida.** Call this paranoia or an abundance of caution or fear if you wish, but **I sense that CDC scientists on cable TV are worried about a pandemic.**

**Disneyworld is taking this coronavirus threat seriously;** some Disney employees who traveled on business to Italy have been asked to stay at home for two weeks on their return and are being checked for fever, etc. See: <https://www.floridatoday.com/story/travel/news/2020/02/26/coronavirus-disney-world-workers-who-traveled-italy-stay-home/4885513002/>

Finally, **Farm Journal's PORK reminds us and Department of Agriculture not to forget African Swine Flu in pigs** while we fight the novel coronavirus. ASF has been shown to jump species just like SARS-CoV-2. See: [https://www.porkbusiness.com/article/foreign-animal-disease-poses-growing-threat-us-agriculture?mkt\\_tok=eyJpIjoiTm9kaE9URXdNRfkyTUdFeClslQjOjIjVVRTQnRCNnU5NExpZ1NZSG9LTU5vR0FGa0JodDdWVDdTb05KNWg2WGxlUUIY0lobWhmT3luY1wvWXZScG1WYWRwUVBhV0QzdDRsR0hcL2RNSW5NWmpFNTNnaVBCVkvMVWIONnlob1hTTHVyNkh2XC84ckNNNTA2aEU2cUhhKc2Q3cyJ9](https://www.porkbusiness.com/article/foreign-animal-disease-poses-growing-threat-us-agriculture?mkt_tok=eyJpIjoiTm9kaE9URXdNRfkyTUdFeClslQjOjIjVVRTQnRCNnU5NExpZ1NZSG9LTU5vR0FGa0JodDdWVDdTb05KNWg2WGxlUUIY0lobWhmT3luY1wvWXZScG1WYWRwUVBhV0QzdDRsR0hcL2RNSW5NWmpFNTNnaVBCVkvMVWIONnlob1hTTHVyNkh2XC84ckNNNTA2aEU2cUhhKc2Q3cyJ9).

Be well,  
RGL, M.D.

*If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: Unsubscribe.*

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

Sent from Outlook

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/26/2020 10:25:45 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group

---

**CC:** (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]

**Subject:** CDC Confirms Possible Instance of Community Spread of COVID-19 in U.S.

<https://www.cdc.gov/media/releases/2020/s0226-Covid-19-spread.html>

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 9:46:46 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

**Subject:** Coronavirus (AShah/KLenihan/SHahn)  
**Location:** Commissioner's Office (WO1/2217)

**Start:** 2/27/2020 2:45:00 PM  
**End:** 2/27/2020 3:00:00 PM  
**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan; Shah, Anand



---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 9:46:46 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

**Subject:** Coronavirus (AShah/KLenihan/SHahn)

**Location:** Commissioner's Office (WO1/2217)

**Start:** 2/27/2020 2:45:00 PM

**End:** 2/27/2020 3:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan; Shah, Anand

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5fdeb7f3d-Heather.Jan]; Caligui, Laura (Laura.Caligui@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Od4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer] CC: Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Mettler, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Phucas, Kristin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f6eebdb15f044faa71708e7c4b73ab2-PhucasK]; Boam, Ashley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50d98ccb05de40009c137d62c7e02bc1-AAB]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Attachments:** SH Conrovirus Hearing.HELP Prep Agenda\_final.docx

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,,,"

(b)(6)

**Start:** 3/2/2020 1:30:00 PM

**End:** 3/2/2020 2:00:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguirri, Laura (Laura.Caliguirri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F; Kumar, Dinesh; Beers, Donald

Agenda Added: 3/2/2020

Please note new start time of 1:30 pm, as well as new end time of 2:00 pm.

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbec5ffeb7f3d-Heather.Jan]; Caliguir, Laura (Laura.Caliguir@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Kumar, Dinesh  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]

**CC:** Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Mettler, Erik  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 3/2/2020 1:15:00 PM

**End:** 3/2/2020 2:20:00 PM

**Show Time As:** Busy

**Required Attendees:** Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Amin, Stacy; McWilliams, Carly; Janik, Heather; Caliguiri, Laura; McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F; Kumar, Dinesh; Beers, Donald

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer] CC: Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Mettler, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Phucas, Kristin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f6eebdb15f044faa71708e7c4b73ab2-PhucasK]; Boam, Ashley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50d98ccb05de40009c137d62c7e02bc1-AAB]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Attachments:** SH Conrovirus Hearing.HELP Prep Agenda\_final.docx

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,,, (b)(6)

**Start:** 3/2/2020 1:15:00 PM

**End:** 3/2/2020 2:20:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguirri, Laura (Laura.Caliguirri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F; Kumar, Dinesh; Beers, Donald

Agenda Added: 3/2/2020

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Caligui, Laura (Laura.Caligui@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Od4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group



---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]

**CC:** Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Mettler, Erik  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 3/2/2020 1:15:00 PM

**End:** 3/2/2020 2:20:00 PM

**Show Time As:** Busy

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Abram, Anna; Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; McBride, Maren; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Amin, Stacy; McWilliams, Carly; Janik, Heather; Caliguiri, Laura; McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbbeee5ffeeb7f3d-Heather.Jan]; Caligui, Laura (Laura.Caligui@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Kumar, Dinesh  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]  
**CC:** Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Mettler, Erik  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Phucas, Kristin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f6eebdb15f044faa71708e7c4b73ab2-PhucasK]; Boam, Ashley  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50d98ccb05de40009c137d62c7e02bc1-AAB]; Cavazzoni, Patrizia  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 3/2/2020 1:15:00 PM

**End:** 3/2/2020 2:20:00 PM

**Show Time As:** Busy

**Required Attendees:** Hahn, Stephen; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F; Kumar, Dinesh; Beers, Donald

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer] CC: Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Mettler, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d6200f06754e989ab2a7474222443a-Erik.Mettle]; Phucas, Kristin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f6eebdb15f044faa71708e7c4b73ab2-PhucasK]; Boam, Ashley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50d98ccb05de40009c137d62c7e02bc1-AAB]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Attachments:** SH Conrovirus Hearing.HELP Prep Agenda\_final.docx

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975,, (b)(6)

**Start:** 3/2/2020 1:30:00 PM

**End:** 3/2/2020 2:30:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguirri, Laura (Laura.Caliguirri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F; Kumar, Dinesh; Beers, Donald

Agenda Added: 3/2/2020

Please note new start time of 1:30 pm.

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/27/2020 10:16:40 AM  
**To:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anna Abram - FDA (Anna.Abram@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Maren McBride [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McWilliams, Carly [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Carlyle.McWilliamsa42]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbbeee5ffeeb7f3d-Heather.Jan]; Caliguir, Laura (Laura.Caliguir@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcd41f240d7-Megan.McSev]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Scherf, Uwe

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Cave, Carol  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]

**CC:** Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]

**Subject:** Commissioner Prep: HELP Hearing: An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus

**Location:** Commissioner's Conference Room (WO1/2102) or 1-877-465-7975, (b)(6)

**Start:** 3/2/2020 1:15:00 PM

**End:** 3/2/2020 2:20:00 PM

**Show Time As:** Busy

**Required Attendees:** Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Anna Abram - FDA (Anna.Abram@fda.hhs.gov); Gross, Karas; Shah, Anand; Rom, Colin; Hinton, Denise; Mair, Michael; McMeekin, Judith; Abdoo, Mark; Maren McBride; Black, Jennifer; Tantillo, Andrew; Rath, Prakash (FDA); Woodcock, Janet; Shuren, Jeff; Marks, Peter; Cho, David S (CBER); Clarke, Mary Beth; Stacy Amin - FDA (Stacy.Amin@fda.hhs.gov); McWilliams, Carly; Janik, Heather; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); McSeveney, Megan; Anderson, Erika; Solomon, Steven M; Forfa, Tracey; Agler, Heather L; Scherf, Uwe; Felberbaum, Michael; Cave, Carol; Rogers, Michael; Laska, Susan F

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 10:22:31 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: HOLD: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/27/2020 1:45:00 PM  
**End:** 2/27/2020 2:15:00 PM  
**Recurrence:** (none)



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 10:22:33 AM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 3/4/2020 2:15:00 PM  
**End:** 3/4/2020 2:45:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 10:22:46 AM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: COVID-19 Agency Executive Group meeting  
**Location:** 1-877-465-7975, code: 155 34 900# or COO Conference Room (WO2/3305)  
**Start:** 2/27/2020 5:00:00 PM  
**End:** 2/27/2020 6:00:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 12:13:32 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: HOLD: AMA daily Coronavirus Update  
**Location:** 615-F  
**Start:** 2/27/2020 2:00:00 PM  
**End:** 2/27/2020 2:15:00 PM  
**Recurrence:** (none)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 2:36:30 PM  
**To:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: FYI - response language to Bloomberg

Thx

Sent from my iPad

On Feb 26, 2020, at 3:13 PM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Date:** February 26, 2020 at 3:12:27 PM EST  
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Schipper, Jodi <jodi.schipper@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>  
**Subject:** FW: FYI - response language to Bloomberg  
**Importance:** High

FYI.

*Caitlin*

---

**From:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>  
**Sent:** Wednesday, February 26, 2020 3:10 PM  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Cc:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>  
**Subject:** FYI - response language to Bloomberg  
**Importance:** High

Good afternoon, all – sending language below as an FYI that OMA will send to a reporter with Bloomberg News, who mischaracterized his comments about the potential for a pandemic in [an article](#) that posted after remarks at a meeting. OMA plans to send the following language to the reporter, which with the exception of the last sentence, was taken from the [CDC webpage on risk assessment](#):

**(b)(5)**

Any questions, please let me know.

Thanks –

Lorrie

**Lorrie H. McNeill**

*Director*

●ffice of Communication, ●utreach and Development

Center for Biologics Evaluation and Research

U.S. Food and Drug Administration

Tel: 240-402-8119

lorrie.mcneill@fda.hhs.gov

<image007.jpg>

<image008.jpg>

<image009.jpg>

<image010.jpg>

<image011.jpg>

<image012.jpg>

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 2/27/2020 3:31:05 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** FW: Supply chain updates

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Sent:** Thursday, February 27, 2020 2:41 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Subject:** Supply chain updates

A few updates from today:

(b)(5)

---

**From:** Charrow, Robert (HHS/OGC) [Robert.Charrow@hhs.gov]  
**Sent:** 2/27/2020 3:37:05 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]  
**Subject:** UC Testkit information.

**Importance:** High

Here is the information that was just forwarded to me. B

---

**From:** Rachel Nosowsky <Rachel.Nosowsky@ucop.edu>  
**Sent:** Thursday, February 27, 2020 3:17 PM  
**To:** Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>  
**Subject:** RE: Testkit  
**Importance:** High

OK, just got clarification, here's where we are:

1. We have one lab at the Chan-Zuckerberg Biohub run by Joe Derisi (<https://profiles.ucsf.edu/joe.derisi>) that has been working with the Bill & Melinda Gates Foundation. I understand this lab played a role in the index case in Cambodia and have been helping folks in multiple countries. They believe they can rapidly turn the Biohub into a testing facility capable running several thousand tests/day, using what sounds like the same test that CDC is using. They have the necessary space, infrastructure, molecular biology, and data science teams at the ready. I'm expecting a brief bulleted write-up in the next 20 minutes or so that I can send you to introduce you to this lab. They already work with public health departments and health facilities around the country and would be able and willing to accept kits from throughout California and beyond. They already have BUA to receive inactivated human samples.
2. Derisi's lab and a separate lab run by Charles Chiu are also working on rapid assays using CRISPR technology. Here are a couple of articles. I will have more information for you on the Chiu option later today (he's unavailable before 2pm Pacific).

<https://www.sfchronicle.com/bayarea/article/Coronavirus-UCSF-expert-working-on-quicker-15014490.php>  
<https://www.nytimes.com/2020/02/24/health/genomic-diagnostic-tests.html>  
<https://profiles.ucsf.edu/charles.chiu>

I'm on cell 24/7 if you need anything in the meantime. Cell is (b)(6)

- R

**Rachel Nosowsky**  
University of California  
(b)(6)

---

**From:** Richard J.L. Senior [senior@morganservices.com]  
**Sent:** 2/27/2020 4:27:34 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]  
**CC:** Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]  
**Subject:** There is a cure available NOW for the coronavirus  
**Attachments:** BARDA UBT Rev 5-10-2016.ppt  
**Importance:** High

Dear Dr. Hahn,

Since it mentions the FDA, you may be interested in the e-mail (below) that I sent this morning to Alex Azar.

Sincerely,

Richard J. Senior

\*\*\*

“Dear Dr. Azar,

Yesterday I watched you and Dr. Fauchi talk at the President’s press conference on the COVID-19. Donald Trump is going to be hopping mad when he discovers that there is a highly effective, completely safe and very quick cure for the Coronavirus. Sooner or later, he will hear about it by way of one of the many people I’ve told about the cure including several members of your staff in the CDC, NIH, NIAH, NIAID, NCCAM, FDA, etc. I assume that your people have not seen fit to tell you.

The coronavirus can be cured by a process that has been around for nearly a century. All that is required is to draw about 40cc of blood, dilute it 4 to 1 with saline, add some Heparin to prevent coagulation, pass it through a fused-quartz cuvette (tube) that is transparent to UV and housed in a box containing UV-C bulbs that shine UV-C through the blood on its way to being reinfused at 3-4 drops/second through the same needle used to withdraw it. The UV-C strips the protective cover off some (not all) of the coronaviruses in the 40cc of blood so that the immune system can recognize the live coronaviruses and eradicate them all. THE BODY CURES ITSELF.

The attachment is the presentation on Ultraviolet Blood Therapy (UBT), the universal cure for infections, that the NIH’s Biomedical Advanced Research and Development Authority (BARDA) invited me to give in Washington DC. BARDA is charged with keeping the government up to date with new developments. Even though UBT was discovered in the USA nearly a century ago, and was part of main stream medicine until 1950, conventional medicine in the US now



doesn't know anything about it and doesn't want to know! UBT isn't taught in Medical Schools. The BARDA representatives showed interest but told me that there was no chance that the FDA would approve UBT for use in US hospitals because of the FDA's medical orthodoxy. However, because of UBT's long history of efficacy and complete safety and the fact that it is approved in twenty-seven countries, including the European Community, **the FDA could approve it for COVID-19** under their policy of making individual exceptions for very sick patients. My website [InfectionsCured.com](http://InfectionsCured.com) has details of cures and successful trials abroad in the last 25 years.

**Half a million deaths in America every year from "untreatable" viral and Superbug infections can, and should, be prevented by using UBT to cure those patients.** Moreover, millions more who don't die, suffer unnecessarily. For example, (added: *amputations because of MRSA and*) UBT has cured every case of shingles treated with it eliminating the acute pain and preventing any painful lifetime aftermath of peripheral neuropathy. Once UBT's efficacy and safety is demonstrated for the COVID-19 and the Pandemic is over, I would hope that the FDA would quickly approve UBT for general use.

I have absolutely no direct or indirect financial interest in UBT. I'm just horrified at the shocking deaths and suffering."

Richard J. Senior  
Chicago

(b)(6)

---

This email transmission and any documents, files, or previous email messages attached to it may contain information that is confidential or legally privileged. If you are not the addressee or authorized to receive this message for the addressee, you may not use, copy, or disclose to anyone this message or its contents. If you have received this message in error, please notify the sender immediately and permanently destroy any copies you may have.

---

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/27/2020 5:10:25 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

---

**CC:** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbbeee5ffeeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]

**Subject:** of interest

- Vice President Mike Pence has appointed Debbie Birx, an ambassador-at-large for the State Department who currently focuses on HIV and AIDS, to serve as the "White House Coronavirus Response Coordinator" responsible for leading the administration's strategy on fighting the outbreak. Birx and three new members of the White House's coronavirus task force - Treasury Secretary Steven Mnuchin, Surgeon General Jerome Adams and National Economic Council Director Larry Kudlow - will report to Pence and Health and Human Services Secretary Alex Azar. ([Bloomberg](#) )
- The Centers for Disease Control and Prevention said the agency fixed an issue with the coronavirus test kits it is sending to state health labs, allowing for faster screening and diagnosis of the virus. Azar said 40 local, state and department of defense labs can already use the modified tests, which provide a definitive diagnostic, and by next week all 93 labs will have clearance. ([NPR News](#))

---

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/27/2020 5:10:30 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79cf076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim

---

**CC:** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]  
Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Cho, David S (CBER)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]

**Subject:** RE: COVID-19 Agency Executive Group meeting

**Attachments:** FDA Travel Policy.pptx

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 5:17:06 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 2/28/2020 1:30:00 PM  
**End:** 2/28/2020 2:00:00 PM  
**Recurrence:** (none)

**From:** DLGDESK (HHS/ASPR/OPP) (b)(6)  
**Sent:** 2/27/2020 5:18:09 PM  
**To:** DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Hahn, Stephen (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Engels, Thomas J (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; Collins, Francis S (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; McCance-Katz, Elinore (SHY) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Falcon, Jessica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; OS Salesses, Robert [Robert.g.salesses.civ@mail.mil]; Terry.m.rauch.civ@mail.mil; Caneva, Duane (DHS.GOV) [duane.caneva@hq.dhs.gov]; OS Bibo, David [David.Bibo@fema.dhs.gov]; Kim, Paul (VA.GOV) [paul.kim@va.gov]; Philip.j.ferro@nsc.eop.gov; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Dodgen, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Rucker, Donald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Blatner, Gretta L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-HHS-Gretta.]; Fauci, Anthony S (NIH)



---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Saxon, Bobby (CMS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Bird, Catherine (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Perez-Rivera, Diana (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c224eebfa1e4624b0c22b3b343fe6c7-HHS-Diana.P]; Taitsman, Julie (OIG)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Moudy, Robin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Chang, William (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Strom, John (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Hecht, Jonah (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72f96c98e3cd4181a389a03fef9d3aa6-HHS-Jonah.H]; Cochran, Norris (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Donnelly, Kelsey S (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]

CC: CMS SV1 [SV1@cms.hhs.gov]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; CMS Administrator [CMSAdministrator@cms.hhs.gov]

**Subject:** Disaster Leadership Group (DLG) COVID-19 Response Coordination

**Attachments:** COVID-19-DLG-Agenda-02-28-2020.pdf; ASPR Event Logistics Information\_HHH Building\_ASPR Conference Room.pdf

**Location:** ASPR Main Conference Room, 638G, Humphrey Building, 200 Independence Avenue SW, Washington DC, 20201 | Conference Line: 800-857-5236; Participant Code: DLG

**Start:** 2/28/2020 10:45:00 AM

**End:** 2/28/2020 11:45:00 AM

**Show Time As:** Free

**Recurrence:** (none)

**Update: The meeting agenda and conference line information have been added to this invitation. Just as a reminder, if you plan on dialing into the meeting, please call-in 15 minutes in advance of the meeting start time. Modifications to the distribution list cannot be made after 9:00 AM on Friday, 2/28.**

Dear Disaster Leadership Group (DLG) Members:

The Assistant Secretary for Preparedness and Response (ASPR) will convene a DLG meeting on February 28, 2020 from 10:45 AM to 11:45 AM.

**DLG Intent**

The purpose of this DLG is to gather HHS and interagency senior leaders to provide Departmental updates on COVID-19 activities and discuss coordination and mitigation strategies for current and future activities.

### **Meeting Logistics**

Due to the confidential nature of the information that may be discussed during this forum, we ask that you **DO NOT forward** this meeting invitation to other colleagues. **Please note:** only those listed on the distribution list will be allowed to join the call. Please direct any requests to modify the distribution list for this DLG meeting to the DLGDESK resource mailbox at **(b)(6)**. Requests to modify the distribution list **must be made by 9:00 AM Friday, February 28.**

### **Joining Remotely**

A conference line will be made available for participants to join the meeting remotely. **Please join the conference line at least 15 minutes prior to the start of the meeting.**

**Conference Line:** **(b)(6)**

**Participant Code:** **(b)(6)**

**Participants can join the meeting: [Click here](#)**

This session will also be held in the ASPR Main Conference Room, 638G, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201.

Respectfully,

**Daniel Dodgen, Ph.D.**

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

---

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | [www.phe.gov](http://www.phe.gov)

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/27/2020 5:26:18 PM  
**To:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]  
**CC:** AMA2 (OS/IOS) [AMA2@hhs.gov]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebdddde-HHS-Kyle.Ze]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]  
**Subject:** Re: Shortage

Mr. Secretary  
I called your phone to give you a heads up  
Thx  
Steve

Sent from my iPhone

On Feb 27, 2020, at 5:22 PM, Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov> wrote:

Begin forwarded message:

**From:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Date:** February 27, 2020 at 5:17:39 PM EST  
**To:** "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>, "Steele, Danielle (HHS/IOS)" <Danielle.Steele@hhs.gov>  
**Subject: Fwd: Shortage**

FYI- [REDACTED] (b)(5)

Sent from my iPhone

Begin forwarded message:

**From:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Date:** February 27, 2020 at 3:57:24 PM EST  
**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Subject: Shortage**

[REDACTED] (b)(5)

**(b)(5)**

Sent from my iPhone

**From:** Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]  
**Sent:** 2/27/2020 8:38:00 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Solberg, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]  
**CC:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]  
**Subject:** USFK Service Member Confirmed with COVID-19

<https://www.usfk.mil/Media/News/Article/2094200/usfk-service-member-confirmed-with-covid-19/>

see also USFK Individual Confirmed with COVID-19

<https://www.usfk.mil/Media/News/Article/2091383/usfk-individual-confirmed-with-covid-19/>

---

**From:** Jose E. Garcia, M.D. [josegarcia@americancare.net]  
**Sent:** 2/27/2020 10:20:32 PM  
**To:** FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissioner]  
**Subject:** Medical group with 600 healthcare workers unable to purchase face masks and other personal protection devices.

Dear Commissioner Hahn,

We are a multi-specialty physician group operating outpatient medical centers throughout the State of Florida with approximately (b)(4) healthcare workers (www.americancare.com). The reason for my email is that we are running out of face masks and other personal protection devices. We have been advised by our various vendors that we are in a priority list for such supplies, but that it may be weeks before we get them.

We predominantly provide services to low income elderly patients with chronic conditions. We also operate infectious diseases clinics within our medical centers. (b)(4)

(b)(4)

If we are not able to obtain face masks and other personal protection devices, (b)(4)  
(b)(4)

Your assistance in this matter is of critical importance.

Sincerely,

Jose E. Garcia, Jr. M.D.  
Chief Executive Officer  
American Care  
305-278-0200 Ext. (b)(6)

Privacy Notice: This electronic mail message, and any attachments, are confidential and are intended for the exclusive use of the addressee(s) and may contain information that is proprietary and that may be Individually Identifiable or Protected Health Information under HIPAA. If you are not the intended recipient, please contact the sender immediately telephonically, or by email, and destroy all copies of this message. If you are a regular recipient of our electronic mail, please notify us promptly if you change your email address.

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/27/2020 10:34:48 PM  
**Subject:** Dr. Levitt's COVID-19 Update for 27 Feb 2020  
**Attachments:** CT in Coronavirus.pdf; How SARS CoV 2 Invades Human Cells.pdf

Dear All,

Here are short summaries of the COVID-19 articles I read online or in journals today:

**Mount Sinai** physicians have analyzed the CT findings on greater than 90 COVID-19 patients from China. See: <https://www.mountsinai.org/about/newsroom/2020/mount-sinai-physicians-the-first-in-us-analyzing-lung-disease-in-coronavirus-patients-from-china-press-release>. They have confirmed the **peripheral and posterior ground glass opacity (GGO) pattern that the Chinese have described on CT scans**. See pdf attached above. Note that on CXR the appearance is 'reverse bat wing' infiltrates. CT shows findings before CXR shows findings.

**KWMU** (Saint Louis NPR station) interviewed Rosemary Gibson who wrote *China Rx* today. See: <https://www.madeinamerica.com/china-rx-book-author/> The author says we need to source drugs from U.S. and countries other than China. We are too dependent on Chinese pharmaceuticals she says.

**NYT Parenting Section** today has an article about **whether Spring Break trips should be cancelled**. See: <https://parenting.nytimes.com/health/coronavirus-family-travel-advisory>. The advice is common sense advice including pay attention to CDC Level warning for countries you are planning to visit; use alcohol foam frequently; avoid tray tables and bathrooms on airplanes if you can. Read the CDC bulletins daily before and during your trip. Make sure your travel insurance is 'any cause cancellation' insurance which costs 40% more than standard travel insurance.

**NYT** has Ed/Op on **SARS-Cov-2 being Disease X**, the anticipated viral disease that is highly transmissible and highly deadly. See: [https://www.nytimes.com/2020/02/27/opinion/coronavirus-pandemics.html?te=1&nl=david-leonhardt&emc=edit\\_ty\\_20200227&campaign\\_id=39&instance\\_id=16320&segment\\_id=21680&user\\_id=e37b7ca2e8bae8d104574a7b4a01f953&regi\\_id=6869412220200227](https://www.nytimes.com/2020/02/27/opinion/coronavirus-pandemics.html?te=1&nl=david-leonhardt&emc=edit_ty_20200227&campaign_id=39&instance_id=16320&segment_id=21680&user_id=e37b7ca2e8bae8d104574a7b4a01f953&regi_id=6869412220200227). The author overstates his case. In my opinion, SARS-CoV-2 *may* be Disease X, but isn't yet. The world is coming together and fighting back. The author is correct about all countries needing to do more to prevent Disease X. China needs to shut down all wet markets, prevent black market sale or breeding of bats and other exotic animals for herbalists, destruction of forests and jungles where strange animals live, etc. Every country needs to do this.

**Nature Microbiology** has a research article that says another receptor on human cells in addition to ACE-2 is involved in SARS-CoV-2 penetration of human cells. See pdf above. I wish I knew more microbiology so I could understand the article. I sense that human proteases protect the host human cell and that folding of the spike on the coronavirus is involved with penetration of the host cells, but I cannot go further. Hopefully, one or more readers will know how to proceed with a treatment to prevent human cell penetration by SARS-CoV-2.

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.



*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner*

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 2/28/2020 8:43:50 AM  
**To:** Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Diagnostic Plan  
**Attachments:** Plan to Increase COVID-19 Testing in the US 2-28-20 FINAL.docx

Attached is the plan for discussion at 10:45.

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/28/2020 9:32:29 AM  
**Subject:** Morning Editon of Dr. Levitt's COVID-19 Update for 21 Feb 2020

Dear All,

**WHO's Dr. Tedros** stated today that we are in the 'decisive' week of COVID-19 spread, So I have put together a 'what is good, what is bad' list of COVID-19 related articles from this morning's newspapers.

**St. Louis Post-Dispatch** has a Front Page article on what Saint Louis hospital systems, **esp. SSM**, are doing to combat the spread of this novel coronavirus. See: [https://www.stltoday.com/lifestyles/health-med-fit/health/getting-ready-st-louis-hospital-systems-and-health-departments-prepare/article\\_6f163147-4ed6-545a-8edf-ec6efce14e38.html](https://www.stltoday.com/lifestyles/health-med-fit/health/getting-ready-st-louis-hospital-systems-and-health-departments-prepare/article_6f163147-4ed6-545a-8edf-ec6efce14e38.html).

If you read this article, you will see that locally within and between hospital systems doctors are working together to prepare for the worst while hoping for the best.

**But once you get beyond the local level, the dynamics change because politics takes over in my opinion.** The head of Missouri's health departments stated that 60 people in Missouri are being tested for COVID-19, but I have only read about one person being tested. And I read a lot. There are other troubling articles nationally as well:

**Washington Post** reports today that **HHS workers met Americans airlifted from Wuhan without wearing any personal protective gear (PPE)**. These workers were working alongside CDC workers completed clothed in PPE. How does this happen? Why didn't CDC workers divide up the PPEs and share with HHS workers. Why was untrained HHS team leader placed in charge of his/her workers? I blame politics. See: <https://www.washingtonpost.com/health/2020/02/27/us-workers-without-protective-gear-assisted-coronavirus-evacuees-hhs-whistleblower-says/> (Secretary Azar will not let this happen again)

**Paul Krugman in NYT** this morning blames President Trump. See: [https://www.nytimes.com/2020/02/27/opinion/coronavirus-trump.html?te=1&nl=david-leonhardt&emc=edit\\_ty\\_20200228&campaign\\_id=39&instance\\_id=16352&segment\\_id=21716&user\\_id=e37b7ca2e8bae8d104574a7b4a01f953&regi\\_id=6869412220200228](https://www.nytimes.com/2020/02/27/opinion/coronavirus-trump.html?te=1&nl=david-leonhardt&emc=edit_ty_20200228&campaign_id=39&instance_id=16352&segment_id=21716&user_id=e37b7ca2e8bae8d104574a7b4a01f953&regi_id=6869412220200228)

That's just not true. **It's Washington, D.C. politics we should blame. 'It's all politics, all the time' I have been told by an insider.** So public servants must stand tall and speak up when they know they don't know or have the answer. Everyone so far has bent to the President's demands, but he is a businessman, not a doctor or scientist.

So let's pay attention to the scientists and **provide politicians with their personal scientists to keep the response to COVID-19 on track. Provide Vice President Pence with Surgeon General Adams as his scientist/doctor. Give Dr. Fauci or Dr. Redman a Cabinet level position to call the shots as they see them.** Keep the public service announcements coming on cable TV and public TV. If the CDC testing kits don't work today, **buy all the kits we can from Norway and Germany** (those are the kits China uses). Follow Dr. Starkloff's action plan for the 1918 Influenza Epidemic in Saint Louis (prior email to all). **Do what Pasteur did for smallpox and Dr. Gallagher did for measles in Pottstown, PA in 1934.** See: <https://www.wsj.com/articles/how-a-boys-blood-stopped-an-outbreak-11582847330>

Finally, China isn't free of blame either. **Commissioner Feng's Op/Ed this morning in the NYT is lacking.** See: <https://www.nytimes.com/2020/02/28/opinion/coronavirus-china->

government.html?te=1&nl=david-leonhardt&emc=edit ty 20200228&campaign id=39&instance id=16352&segment id=21716&user id=e37b7ca2e8bae8d104574a7b4a01f953&regi id=6869412220200228.

China hid the outbreak's numbers earlier, left the wet markets open too long (since SARS), held up CDC's mission to China, punished the doctors who recognized the outbreak early, and as all autocratic regimes denied bad news in country. China provides no 'live' email address to send emails to the PRC leaders or Washington, D.C. embassy.

Be well,  
RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner*

**From:** Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]  
**Sent:** 2/28/2020 10:23:11 AM  
**To:** Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c243d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH)

---

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]

**CC:** Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]

**Subject:** HHS COVID-19 Response - alignment of OPDIV/STAFFDIV Efforts

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to: (b)(6) no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec  
ASPR

---

**From:** Zebley, Kyle (HHS/OS/OGA) [Kyle.Zebley@hhs.gov]  
**Sent:** 2/28/2020 10:55:28 AM  
**To:** Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fc1b527694276af1ccdb7db495042-HHS-Brian.S]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Hahn, Stephen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Ford-Barnes, Arwenitha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenitha]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6fafe2d8d4791dad4-HHS-William]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Stecker, Judy (OS)

---

[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facfe0846fc-HHS-Judy.St]

**Subject:** Today's Agenda for AMA Daily Coronavirus Update

**Attachments:** Agenda for AMA Briefing - Novel Coronavirus - 02.28.2020.docx

Good morning,

Attached, and copy and pasted below, please find the agenda for today's AMA Daily Coronavirus Update. Please note where your Staff or Operating Division are noted on the agenda, and be prepared to update the Secretary appropriately.

Thanks,  
Kyle

**Briefing Agenda:**

1. **Update on Program Management (Deputy Chief of Staff Paul Mango)**
2. **Supplies (ASPR/FDA)**
  - a. **Vaccine**
  - b. **Therapeutics**
  - c. **PPE**
  - d. **Affordability and Access**
3. **Supply chain (ASPR/FDA)**
  - a. **Pharma products**
  - b. **Devices**
  - c. **Medical supplies**
4. **Containment (CDC/FDA/ASPR)**
  - a. **Diagnostics**
  - b. **Travel Measures (advisories, screening, 212(f))**
  - c. **Trigger plan to mitigation**
  - d. **Communications and education for healthcare providers**
5. **Mitigation (CDC/ASPR)**
  - a. **Treatment advice**
  - b. **Mitigation measures**
  - c. **Hospital capacity assessment and enhancement plans**
6. **External (ASPA/ASL/IEA)**
  - a. **Communications regarding mitigation for the public and others**

Kyle Zebley  
Chief of Staff  
Office of Global Affairs (OGA)  
Office of the Secretary  
U.S. Department of Health and Human Services  
Direct: 202-260-6494/Mobile: (b)(6)

*Confidential and pre-decisional communication*



---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/28/2020 2:46:15 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]  
**CC:** Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]  
**Subject:** FW: Letter on FDA Inspection Personnel and Coronavirus  
**Attachments:** LETTER\_FDA on Inspection Personnel and Coronavirus 2.28.20.pdf

See the attached letter from Murray and others on inspections and inspections personnel. We'll start working it through the process.

---

**From:** Backfield, Katlin McKelvie (HELP Committee) <Katlin\_Backfield@help.senate.gov>  
**Sent:** Friday, February 28, 2020 2:26 PM  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** FW: Letter on FDA Inspection Personnel and Coronavirus

FYI

---

**From:** Penna, Alyssa (Van Hollen) <Alyssa\_Penna@vanhollen.senate.gov>  
**Sent:** Friday, February 28, 2020 2:21 PM  
**To:** Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Cc:** Duggan, Abigail (Brown) <Abigail\_Duggan@brown.senate.gov>; Backfield, Katlin McKelvie (HELP Committee) <Katlin\_Backfield@help.senate.gov>; McKinney, Nikki (HELP Committee) <Nikki\_McKinney@help.senate.gov>; Allen, Kerry (Hirono) <Kerry\_Allen@hirono.senate.gov>; Jee, Lauren (Cardin) <Lauren\_Jee@cardin.senate.gov>  
**Subject:** Letter on FDA Inspection Personnel and Coronavirus

Hi Michael,

I hope you're doing well. Please see attached letter from Senator Van Hollen, Brown, Cardin, Hirono, and Murray.

Best,  
Alyssa

**Alyssa Penna**  
**Health Policy Advisor**  
Office of Senator Chris Van Hollen  
110 Hart Senate Office Building  
Washington, DC 20510

(b)(6)

[Alyssa\\_Penna@vanhollen.senate.gov](mailto:Alyssa_Penna@vanhollen.senate.gov)

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/28/2020 2:59:53 PM  
**To:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Beshara, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f32bd7ce179840ceac573964f31216c7-Nicholas.Be]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Beardsley, Sara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bd25fcbe164d44b734711fb17f15b5-Sara.Beards]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]  
**Subject:** FDA Heads Up for HHS NN - 2/29/20 through 3/2/20

**INTERNAL MANAGEMENT DELIBERATIVE - THIS EMAIL SHOULD NOT BE SHARED WITH HHS OP-DIVS. IT MAY CONTAIN CONFIDENTIAL AND/OR SENSITIVE INFORMATION.**

Planned for 2/29/20 - 3/2/20:

**(b)(5)**

**(b)(5)**

**From:** Fucci, Michael (OS/ASPR/SPPR) (CTR) [Michael.Fucci@hhs.gov]  
**Sent:** 2/28/2020 3:39:15 PM  
**To:** Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Hahn, Stephen (HSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Engels, Thomas J (HSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Phillips, Sally (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbcb326c5e670d41c-HHS-Jonatha]; Waters, Cicely (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Imbriale, Samuel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Cooper, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Falcon, Jessica (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]; DeBord, Kristin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; OS Secretaryps Operations Center [hhs.soc@hhs.gov]; OS Salesses, Robert [Robert.g.salesses.civ@mail.mil]; Terry.m.rauch.civ@mail.mil; Caneva, Duane (DHS.GOV) [duane.caneva@hq.dhs.gov]; OS Bibo, David [David.Bibo@fema.dhs.gov]; Kim, Paul (VA.GOV) [paul.kim@va.gov]; Philip.j.ferro@nsc.eop.gov; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Fucci, Michael (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Dodgen, Daniel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Kerr, Lawrence (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Rucker, Donald (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Hinton, Denise

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Patel, Anita (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Blatner, Gretta L (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-HHS-Gretta.]; Fauci, Anthony S (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Perez-Rivera, Diana (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c224eebfa1e4624b0c22b3b343fe6c7-HHS-Diana.P]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Hecht, Jonah (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72f96c98e3cd4181a389a03fef9d3aa6-HHS-Jonah.H]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Hargan, Eric D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70d0bd4c4cf344da9cba4fdcccaee721-HHS-Eric.Ha]; Callahan, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec339fe2bb494b829a3cb4b638466afb-HHS-Kenneth]; Brady, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a0af371df94b4fbee7821e5892048-HHS-William]; Asher, Jason (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f026ebf942de4865944a935e4b2106dd-HHS-Jason.A]; Clay, Matt A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd2be2512f44fae9f59ac4aa02820c9-HHS-Matt.Cl]

**CC:** CMS SV1 [SV1@cms.hhs.gov]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; CMS Administrator [CMSAdministrator@cms.hhs.gov]

**Subject:** Distribution: Summary of Issues - COVID-19 Disaster Leadership Group (DLG) - February 28, 2020  
**Attachments:** COVID-19-DLG-SummaryofIssues-FINAL-02282020.docx; Environmental Stability of SARS-CoV-2 vs. SARS-CoV.pptx

Dear Disaster Leadership Group (DLG) Members,

This email serves to transmit the attached Summary of Issues prepared for the COVID-19 DLG convened on February 28, 2020. We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message.

Additionally, please see attached the slide from NIH regarding the environmental stability of SARS-CoV-2.

Please forward any questions or concerns related to this document to me, the DLG Policy Lead for this forum at Daniel.Dodgen@hhs.gov and kindly cc: DLGDESK@hhs.gov on any communications.

Thank you,

**Daniel Dodgen, Ph.D.**

Senior Advisor  
Office of the Assistant Secretary for Preparedness and Response (ASPR)  
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

of (b)(6)

Daniel.Dodgen@HHS.Gov | [www.phe.gov](http://www.phe.gov)



**From:** Schmoyer, Michael (OS/ONS) [Michael.Schmoyer@hhs.gov]  
**Sent:** 2/28/2020 4:20:52 PM  
**To:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Brady, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a0af371df94b4fbee7821e5892048-HHS-William]; Keckler, Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8266aa627004be49348c9b1400c6e06-HHS-Charles]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Olson, Carolyn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8db4f1f2c22349619deb3e7723f87e4f-HHS-Carolyn]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Harder, Kristina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a27fdbe16947fcb4a0c7caad82aa32-HHS-Kristin]; Robinson, Wilma (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cb06883191e4f6e8d324d78743b27ad-HHS-Wilma.R]; Stirrup, Heidi (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f466d5c45cfd47d88cd4c10282849ce1-HHS-Heidi.S]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Royce, Shannon (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3d87b609bb462e90777e39aef3d4bf-HHS-Shannon]; Wright, Don (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=152e9995ecbe426da71c17c98dafc8aa-HHS-Don.Wri]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Rucker, Donald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; Sigounas, George (HRSA) [GSigounas@hrsa.gov]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Wolfe, Mitchell (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6a21848015074b41965a8925c65edf21-HHS-msw6-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Parker, Jim (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e0601902140f426e9c5a139f7134a3c5-HHS-Jim.Par]; Coquis, Roberto J (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d5a9cd573f544de5b339447cf627fbc-HHS-Roberto]; Kellogg, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Morse, Trent (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ae0038608fc74b6186ad35dbb4abe165-HHS-Trent.M]; Lukens IV, Mel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aaa0ae6a04b943ec9d926f56f4c50b50-HHS-Mel.Luk]; Robinson, William (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=552acd8e8ed14541af143c0f68ed4487-HHS-William]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcc02744b3a6-HHS-carrie.]; Tabak, Lawrence A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0037b2fbba164f33a24944311b80393e-HHS-Lawrenc]

CC: Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Callahan, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ec339fe2bb494b829a3cb4b638466afb-HHS-Kenneth]; Owens, Arne W (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=29dcc5bdf3ff4670b2076ff9995b70cd-HHS-Arne.Ow]; Encarnacion, Dolkie (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b025d82dd719476195fe4cf5fc137c23-HHS-Dolkie.]; Campbell, Amanda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a88bfd63aaaf4a5398fddd4e28849e43-HHS-ons3-cd]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Aguirre, Lisa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba0f7b7f6f442f8d00727396a5c331-HHS-Lisa.Ag]

**Subject:** (CUI) HHS Senior Leadership OSINT Bulletin 2.21.20 and 2.28.20

**Attachments:** OSINT Bulletin Weekly 2.21.20.pdf; OS Feedback Form.pdf; OSINT Bulletin Weekly 2.28.20.pdf; smime.p7s

## CONTROLLED UNCLASSIFIED INFORMATION

Good afternoon-

Information within these bulletins is **CONTROLLED UNCLASSIFIED INFORMATION** and is limited to USG employees /and/ those senior leaders and their staff with a need-to-know. In regards to current world events, ONS is in frequent communication with our National Security and Federal Law Enforcement partners and regularly adjust our operations to account for any identified threats. Should you have specific questions, please feel free to reach out to us.

The Office of National Security is the HHS point of contact for the Intelligence Community, and is responsible for coordination with the Intelligence Community and for intelligence support to HHS senior policy makers and consumers of intelligence across the Department. To assist in accomplishing this, the Intelligence and Analysis Division's Open Source Intelligence (OSINT) team publishes products based off the Secretary's intelligence priorities and informational requirements of the Department's agencies. The attached HHS OSINT bulletin is a weekly informational brief to provide strategic information to protect and defend the Department; raise awareness and knowledge of current emerging threats; and to strengthen stakeholder engagement, governance, and advocacy. Items in this bulletin complement national security-related materials that ONS provides within our secure spaces.

Please provide us feedback and/or additional requirement needs you may want to see in the future.

Very respectfully,

Michael Schmoyer, Ph.D

National Security Advisor to the Secretary

Director, Office of National Security

Immediate Office of the Secretary

CAPT, USPHS

SchmoyerM@HHS.ID.IC.GOV

VOIP: (b)(6)

**CONTROLLED UNCLASSIFIED INFORMATION**

**WARNING: This document is designated CONTROLLED UNCLASSIFIED INFORMATION (CUI). It may contain information that is LAW ENFORCEMENT SENSITIVE (LES) and exempt from public release under the Freedom of Information Act (5USC552). This document is to be controlled, handled, transmitted, distributed, and disposed of in accordance with DHS policy relating to FOUO information, and is not to be released to the public or personnel who do not have a valid need to know without prior approval from ONS.**

---

**From:** Robert Levitt (b)(6)  
**Sent:** 2/28/2020 4:24:10 PM  
**Subject:** Afternoon Update of Dr. Levitt's COVID-19 Update for 28 February 2020  
**Attachments:** COVID-19 in 1100 China Patients.pdf; Bill Gates Perspective.pdf; Fauci Editorial.mht

Dear All,

**NEJM** this afternoon posted online **three very important articles re: COVID-19**. Because of their importance and the WHO increase in threat level today, I have prepared an afternoon edition of my Update before the weekend begins. I thank the NEJM for releasing these articles prior to the weekend. I know that Update recipients have been busy in meetings all day today and have not seen these articles. SARS-CoV-2 will not take the weekend off and neither will our public servants I'm certain. Thank you all.

**Bill Gates** has written a 'what needs to be done' Perspective for the Journal. See pdf attached above. As you know the Bill and Melinda Gates Foundation has donated at least \$100 Million to the effort to end the spread of COVID-19 and treat infected patients, esp. in low or middle income countries; e.g., sub-Saharan Africa. Gates lists what needs to be done; all efforts involve cooperation between countries and huge investments of money.

**Guhan, et. al.** have reported in the Journal the **clinical characteristics of the largest group of COVID-19 patients to date: 1099 patients**. See pdf above. Note no patient included in this sample population was lost to follow-up. Because we are entering the weekend I have abstracted the Guhan report below:

*Sample population represent 15% of patients hospitalized with COVID-19 in China. Only 5% were admitted to the ICU; 2.3% had mechanical ventilation; 1.4% died. 72% of non-Wuhan patients had contact with Wuhan residents. Diagnosis confirmed by RT-PCR. Nearly 90% had fever; 66% had cough. Increasing age and comorbidities increased the risk of COVID-19, but only by 20%. CT scans showed ground glass opacities (GGO) in non-severe and severe cases; GGO were greater in the severe cases; distribution was peripheral and posterior (reverse bat wing on CXR) by my review of Supplementary Appendix CT images. No CT abnormalities in 18% of non-severe cases and 3% of severe cases. Lymphopenia (<1500/cm<sup>3</sup>) was seen in 88% of cases; thrombocytopenia and leukopenia in 33% of cases. Patients were treated with antibiotics, anti-virals, some with steroids, oxygen. Average hospital stay was 12 days for those discharged at time of publication.*

**Fauci, et. al.** have an Editorial re: Guhan report. See pdf attached above. Authors note that the incubation period is 9-12 days so there is an interval to treat infected patients before the disease becomes manifest. But we need a treatment to do this. NIAID, CDC in U.S. and the Chinese CDC have hundreds of ongoing clinical trials. The authors emphasize that this epidemic can be controlled before its pandemic, but only if the whole world pulls together.

Note that the **BBC** today reports 210 deaths among 388 infected Iranian patients. This is a very large discrepancy compared to the 34 deaths reported by the Iranian government. If the BBC investigators who went to Iranian hospitals are correct, the next question is whether the excess deaths were due to lack of ICUs or equipment or whether the SARS-CoV-2 infecting Iran has mutated from coronavirus infecting China. See: <https://www.bbc.com/news/world-middle-east-51673053>.

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: *Unsubscribe*.

*Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.*

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/28/2020 4:48:11 PM  
**To:** Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]  
**Subject:** Accepted: AMA daily Coronavirus Update  
**Location:** 610-F  
**Start:** 3/2/2020 2:00:00 PM  
**End:** 3/2/2020 2:30:00 PM  
**Recurrence:** (none)

---

**From:** Ford-Barnes, Arwenithia (OS) [Arwenithia.FordBarnes@hhs.gov]  
**Sent:** 2/28/2020 5:19:14 PM  
**To:** Kadlec, Robert P (OS) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwenithia (OS); Waters, Cicely (OS); Shuy, Bryan (OS); Callahan, Victoria (OS); Moreno, Rafael (OS); Trueman, Laura (OS); Rowell, Scott (OS); Bird, Catherine (OS); Moughalian, Jen C (OS); Arbes, Sarah C (OS); Murphy, Ryan (OS); Destro, Brenda (OS); Giroir, Brett (OS); Severino, Roger (OS); Grigsby, Garrett G (OS); Kerr, Lawrence (OS); Charrow, Robert (OS); Grimm, Christi A (OIG); Griswold, Nancy J (OS); Op Divs; Johnson, Lynn (ACF); Robertson, Lance (ACL); Khanna, Gopal (AHRQ); Redfield, Robert R (CDC); Verma, Seema (CMS); Saxon, Bobby (CMS); Hahn, Stephen; Hinton, Denise; Engels, Thomas J (HRSA); Weahkee, Michael (IHS); McCollum, Jeffrey (IHS); Frazier, Francis (IHS); Collins, Francis S (NIH); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); McCance-Katz, Elinore (SAMHSA); Krohmer, Jon (dot.gov)  
**Subject:** HHS COVID-19 Response - alignment of OPDIV/STAFFDIV Efforts  
**Location:** Thomas P. O'Neill Federal Building - 200 C Street SW | Washington, DC 20515  
**Start:** 3/4/2020 9:00:00 AM  
**End:** 3/4/2020 10:15:00 AM  
**Show Time As:** Free

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to **(b)(6)** no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec  
ASPR

POC:

**Cicely L. Waters**

Director, Office of External Affairs

Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

200 C St, SW Washington, D.C. 20201

(o) 202-205-0714 (m)

(b)(6)

cicely.waters@hhs.gov



---

**From:** Ford-Barnes, Arwenthia (OS) [Arwenthia.FordBarnes@hhs.gov]  
**Sent:** 2/28/2020 5:19:14 PM  
**To:** Kadlec, Robert P (OS) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwenthia (OS); Waters, Cicely (OS); Shuy, Bryan (OS); Callahan, Victoria (OS); Moreno, Rafael (OS); Trueman, Laura (OS); Rowell, Scott (OS); Bird, Catherine (OS); Moughalian, Jen C (OS); Arbes, Sarah C (OS); Murphy, Ryan (OS); Destro, Brenda (OS); Giroir, Brett (OS); Severino, Roger (OS); Grigsby, Garrett G (OS); Kerr, Lawrence (OS); Charrow, Robert (OS); Grimm, Christi A (OIG); Griswold, Nancy J (OS); Op Divs; Johnson, Lynn (ACF); Robertson, Lance (ACL); Khanna, Gopal (AHRQ); Redfield, Robert R (CDC); Verma, Seema (CMS); Saxon, Bobby (CMS); Hahn, Stephen; Hinton, Denise; Engels, Thomas J (HRSA); Weahkee, Michael (IHS); McCollum, Jeffrey (IHS); Frazier, Francis (IHS); Collins, Francis S (NIH); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); McCance-Katz, Elinore (SAMHSA); Krohmer, Jon (dot.gov)  
**Subject:** HHS COVID-19 Response - alignment of OPDIV/STAFFDIV Efforts  
**Location:** Thomas P. O'Neill Federal Building - 200 C Street SW | Washington, DC 20515  
**Start:** 3/4/2020 9:00:00 AM  
**End:** 3/4/2020 10:15:00 AM  
**Show Time As:** Tentative

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to **(b)(6)** no later than **Monday, March 2 at 12:00 PM**, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec  
ASPR

POC:

**Cicely L. Waters**

Director, Office of External Affairs

Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

200 C St, SW Washington, D.C. 20201

(o) 202-205-0714 (m) **(b)(6)**

[cicely.waters@hhs.gov](mailto:cicely.waters@hhs.gov)

---

**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 2/28/2020 5:25:30 PM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]  
**Subject:** RE: FOR SH Clearance OCC-CLEARED REVISED Supply chain statement tweets

It's captured under the 2nd thread in the 1st and 2nd bullets.

---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Date:** February 28, 2020 at 5:13:36 PM EST  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Subject:** RE: FOR SH Clearance OCC-CLEARED REVISED Supply chain statement tweets

It has been disclosed so I believe it is appropriate.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Friday, February 28, 2020 5:00 PM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Subject:** Re: FOR SH Clearance OCC-CLEARED REVISED Supply chain statement tweets

Look good. Any reason not to disclose that there is one drug shortage related to CV?

Sent from my iPhone

On Feb 28, 2020, at 4:56 PM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Sir  
Attached are tweets for your clearance. Please let me know your approval or comment. Thank you.  
Laura

**Supply Chain Tweets**  
**@SteveFDA Account**  
**Individual tweets--- To be spread out**

(b)(5)

3/1/20

2. See my update on how @US\_FDA is monitoring the supply chain of FDA-regulated products and working to mitigate shortages during the #coronavirus outbreak: [LINK TO SUPPLY CHAIN STATEMENT]

(b)(5)

2/29/20

**Thread 1—Drug shortage:**

1. FDA has been made aware of a human drug that was recently added to the drug shortages list. The manufacturer notified us that this shortage is related to a site affected by #COVID19: [the link belongs here]
2. The shortage is due to an issue with manufacturing an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients.
3. We are working with the manufacturer of this drug as well as other manufacturers to mitigate this shortage and will do everything possible to mitigate it. #COVID19
4. We have contacted over 180 human drug manufacturers to remind them of applicable legal requirements for notifying FDA of anticipated supply disruptions & to ask them to evaluate their entire supply chain, including active pharmaceuticals & other components manufactured in China.

2/29/20

**Thread 2-- PPE:**

1. We are currently not aware of specific widespread shortages of medical devices. [LINK TO SUPPLY CHAIN STATEMENT]
2. FDA has heard of increased demand & supply challenges of personal protective equipment (PPE)—gowns, gloves, surgical masks and/or respirator protective devices, or other equipment designed to protect the wearer from injury or the spread of infection or illness due to #COVID19

(b)(5)

4. We understand there are concerns about availability of PPE because of increased demand during the #COVID19 outbreak. This is not unexpected. If these supply challenges happen, we work closely with healthcare systems and local & regional health officials.

Week of 3/3/20

**Thread 3—Blood/Biologics:**

1. FDA is not aware of any cellular or gene therapies manufactured in China, and has identified no shortages of biologics as a result of supply chain disruptions from #COVID19 to report at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. The potential for transmission of #coronavirus by blood and blood components is unknown at this time; however, respiratory viruses, in general, are not known to be transmitted by blood transfusion.
3. There are no reported cases of transfusion-transmitted #COVID19.
4. The FDA has made information available to blood establishments and to establishments that manufacture human cells, tissues, or cellular or tissue-based products who may wish to consider additional donor screening measures in response to the #COVID19 outbreak.

3/2/20

**Thread 4—Animal drugs:**

1. There are 32 animal drug firms that make finished drugs in or source active pharmaceutical ingredients from China. @US\_FDA has contacted all 32 firms & currently none have reported shortages as a result of #COVID19 at this time: [LINK TO SUPPLY CHAIN STATEMENT]

2. Although none of these 32 animal drug manufacturers have reported a shortage at this time, 6 firms have indicated that there have been disruptions in the supply chain that could soon lead to shortages. FDA is working with these firms to help identify interventions to mitigate any potential shortages.

Week of 3/3/20

**Thread 5—Budget Proposal**

1. The @US\_FDA is using all our existing authorities to address #COVID19 and we welcome the opportunity to work with Congress to strengthen our #coronavirus response capabilities.

2. There are 4 specific proposals included in the President’s FY 2021 budget that would better equip the agency to prevent or mitigate medical product shortages. Learn more about FDA’s budget request: [LINK TO SUPPLY CHAIN STATEMENT]

**@US\_FDA Account  
Individual Tweets**

**(b)(5)**

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Shellooe, Ryan P. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Hurst, Natalie R. EOP/OVP (b)(6); AMA2@HHS.GOV; as2ktc (b)(6); BiegunSE (b)(6); Bigley, Mark C. EOP/OMB (b)(6); Devin.O'Malley@treasury.gov; WILLIAM.FERRARA (b)(6); Grisham, Stephanie A. EOP/WHO (b)(6); Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Miller, Katie R. EOP/OVP (b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC (b)(6); Conant, Ann M. EOP/OMB (b)(6); Conley, Sean P. CDR USN WHMO/WHMU (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL Chief of Staff Office (b)(6); donna.oberry@dot.gov; Duffey, Michael P. EOP/OMB (b)(6); Eisenberg, John A. EOP/WHO (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Grogan, Joseph J. EOP/WHO (b)(6); Hemme, Jake W. EOP/NSC (b)(6); Hennessey, Millicent S. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kan, Derek T. EOP/OMB (b)(6); Kenneth.p.rapuano.civ (b)(6); Liddell, Christopher P. EOP/WHO (b)(6); Miller, Julie L. EOP/OMB (b)(6); Mulvaney, Mick M. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Robert.g.saleesses.civ (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Pottinger, Matthew F. EOP/WHO (b)(6); Riggs, Charlotte R. EOP/WHO (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ruggiero, Anthony J. EOP/NSC (b)(6); Scher, Adam A. EOP/OMB (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulylyot, John L. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Woolfolk, Jon J. EOP/OVP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; DL OVP NSA EXECSEC (b)(6); Bauer, Zachary C. EOP/OVP (b)(6); Moore, Caroline E. EOP/WHO (b)(6); Galkowski, James J. EOP/WHO (b)(6); OVPSchedule (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Troye, Olivia EOP/NSC (b)(6); Loyetc (b)(6); HattinghEF (b)(6); NanavattyKE (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Cavanaugh, Brian J. EOP/NSC (b)(6)  
**CC:** Thurston, Eliza C. EOP/OVP (b)(6); Scully, Bethany S. EOP/OVP (b)(6); Stickles, Brendan R. EOP/OVP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; McBride, Emily J. EOP/WHO (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Paz, Brooke L. EOP/WHO (b)(6)

---

**Subject:** COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants + Materials + Seating Chart  
**Attachments:** UPDATED - Supply Chain Options - N95 (PPE).docx; Task Force Agenda 2.29.2020 1000.docx; VPOTUS COVID19 - Seating Chart.pdf; Travel Restrictions Grid.jpg  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Tentative

All,

There will be a **Coronavirus Task Force Principal's Meeting** at **10:00am** in the **White House Situation Room**. Agenda and read-ahead materials attached.

**Please see attached seating chart for approved attendees.**

Thank you,

**Natalie Hurst**

Executive Assistant to the Chief of Staff  
The Office of the Vice President

**(b)(6)**

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Ferro, Phil J. EOP/NSC (b)(6); AMA2@HHS.GOV; as2kctc (b)(6); BiegunSE (b)(6); Devin.O'Malley@treasury.gov; Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hodgson, Christopher M. EOP/OVP (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO (b)(6); donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Hoelscher, Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kenneth.p.rapuano.civ (b)(6); Robert.g.salesses.civ (b)(6); Pataki, Tim A. EOP/WHC (b)(6); Pottinger, Matthew F. EOP/WHO (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulyot, John L. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Lin, Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; WILLIAM.FERRARA (b)(6); Loyetcj (b)(6); HattinghEF (b)(6); NanavattyKB (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Coronavirus Task Force Principals Meeting - 10:00am  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Tentative

All,

There will be a **Coronavirus Task Force Principal's Meeting** tomorrow morning at **10:00am in the White House Situation Room**. More details and an agenda will be forthcoming.

If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting.

**WAVES Link:** (b)(6)

Participants:



Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Kenneth P. Rapuano, Assistant Secretary of Defense for Homeland Defense and Global Security

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

**Natalie Hurst**

Executive Assistant to the Chief of Staff

The Office of the Vice President

(b)(6)

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Ferro, Phil J. EOP/NSC (b)(6); AMA2@HHS.GOV; as2ktc (b)(6); BiegunSE (b)(6); Devin.O'Malley@treasury.gov; Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7efbef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hodgson, Christopher M. EOP/OVP (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO (b)(6); donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Hoelscher, Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kenneth.p.rapuano.civ (b)(6); Robert.g.salesses.civ (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Pottinger, Matthew F. EOP/WHO (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381fbbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulliyot, John L. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Lin, Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; WILLIAM.FERRARA (b)(6); Loyetc (b)(6); HattinghEF (b)(6); NanavattyKE (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]

**Subject:** Coronavirus Task Force Principals Meeting - 10:00am

**Location:** WHSR JFK

**Start:** 2/29/2020 10:00:00 AM

**End:** 2/29/2020 11:00:00 AM

**Show Time As:** Tentative

-----Original Appointment-----

**From:** Short, Marc T. EOP/OVP (b)(6)

**Sent:** Friday, February 28, 2020 5:23 PM

**To:** Short, Marc T. EOP/OVP; Ferro, Phil J. EOP/NSC; AMA2@HHS.GOV; as2ktc (b)(6); BiegunSE (b)(6); Devin.O'Malley@treasury.gov; Blair, Robert B. EOP/WHO; Harrison, Brian (OS); Hodgson, Christopher M. EOP/OVP; Amie Kalsbeek (DOT); Butterfield, Nicholas W. EOP/WHO; Cetron, Martin (CDC); Chafin, Kelly B. EOP/NSC; Conrad, Patricia L (NIH); Davis, May M. EOP/WHO; donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC; Fauci, Anthony S (NIH); Hoelscher, Douglas L. EOP/WHO; Jacqueline.Colli@va.gov; Kenneth.p.rapuano.civ (b)(6); Robert.g.salesses.civ (b)(6); Pataki, Tim A. EOP/WHO; Pottinger, Matthew F. EOP/WHO; Redfield, Robert R (CDC); Kadlec, Robert P (OS); Joel.Szabat@dot.gov; Tignor, Beth (OS); Ulliyot, John L. EOP/NSC; Williams, Michael B. EOP/WHO; Wilson, John Mark M. EOP/NSC; Lin, Merry S. EOP/WHO; Zachary.McEntee@treasury.gov; Adams, Jerome (OS); WILLIAM.FERRARA (b)(6); Loyetc (b)(6); HattinghEF (b)(6); NanavattyKE (b)(6); Sheehy, Janice

**Subject:** Coronavirus Task Force Principals Meeting - 10:00am

**When:** Saturday, February 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** WHSR JFK

All,

There will be a **Coronavirus Task Force Principal's Meeting** tomorrow morning at **10:00am in the White House Situation Room**. More details and an agenda will be forthcoming.

**If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting.**

**WAVES Link:** (b)(6)

Participants:

Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

**Natalie Hurst**

Executive Assistant to the Chief of Staff  
The Office of the Vice President

(b)(6)

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Shellooe, Ryan P. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Hurst, Natalie R. EOP/OVP (b)(6); AMA2@HHS.GOV; Stuftt, Julie M. EOP/NSC (b)(6); as2ktc (b)(6); BiegunSE (b)(6); Risch, Carl C (b)(6); Jennifer.L.Naaden@hud.gov; Bigley, Mark C. EOP/OMB (b)(6); Devin.O.Malley@treasury.gov; WILLIAM.FERRARA (b)(6); Grisham, Stephanie A. EOP/WHO (b)(6); Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Miller, Katie R. EOP/OVP (b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC (b)(6); Conant, Ann M. EOP/OMB (b)(6); Conley, Sean P. CDR USN WHMO/WHML (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL Chief of Staff Office (b)(6); donna.oberry@dot.gov; Duffey, Michael P. EOP/OMB (b)(6); Eisenberg, John A. EOP/WHO (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Grogan, Joseph J. EOP/WHO (b)(6); Hemme, Jake W. EOP/NSC (b)(6); Hennessey, Millicent S. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kan, Derek T. EOP/OMB (b)(6); Kenneth.p.rapuano.civ (b)(6); Liddell, Christopher P. EOP/WHO (b)(6); Miller, Julie L. EOP/OMB (b)(6); Mulvaney, Mick M. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Robert.g.saleses.civ (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Pottinger, Matthew F. EOP/WHO (b)(6); Riggs, Charlotte R. EOP/WHO (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ruggiero, Anthony J. EOP/NSC (b)(6); Scher, Adam A. EOP/OMB (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulyot, John L. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Woolfolk, Jon J. EOP/OVP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; DL OVP NSA EXECSEC (b)(6); Bauer, Zachary C. EOP/OVP (b)(6); Moore, Caroline E. EOP/WHO (b)(6); Galkowski, James J. EOP/WHO (b)(6); OVPSchedule (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Troye, Olivia EOP/NSC (b)(6); Loyetcj (b)(6); HattinghEF (b)(6); NanavattyKB (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Cavanaugh, Brian J. EOP/NSC (b)(6);  
**CC:** Thurston, Eliza C. EOP/OVP (b)(6); Scully, Bethany S. EOP/OVP (b)(6); Stickles, Brendan R. EOP/OVP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; McBride, Emily J. EOP/WHO (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative

---

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Paz, Brooke L.  
EOP/WHO (b)(6)

**Subject:** COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants + Materials + Updated Seating Chart  
**Attachments:** UPDATED - Supply Chain Options - N95 (PPE).docx; Task Force Agenda 2.29.2020 1000 (005).docx; 02.29.2020 TAB C  
Travel Restrictions Options Grid.jpg; Seating Chart.PNG  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Tentative

All,

There will be a **Coronavirus Task Force Principal's Meeting at 10:00am** in the **White House Situation Room**.  
Agenda and read-ahead materials attached.

**Please see attached updated seating chart for approved attendees. All other participants will be directed to an overflow room.**

Thank you,

**Natalie Hurst**

Executive Assistant to the Chief of Staff  
The Office of the Vice President

(b)(6)

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Shellooe, Ryan P. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Hurst, Natalie R. EOP/OVP (b)(6); AMA2@HHS.GOV; Stuftt, Julie M. EOP/NSC (b)(6); as2ktd (b)(6); Bieguns (b)(6); Bigley, Mark C. EOP/OME (b)(6); Devin.O'Malley@treasury.gov; WILLIAM.FERRARA (b)(6); Grisham, Stephanie A. EOP/WHO (b)(6); Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Miller, Katie R. EOP/OVP (b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC (b)(6); Conant, Ann M. EOP/OMB (b)(6); Conley, Sean P. CDR USN WHMO/WHMU (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL Chief of Staff Office (b)(6); donna.oberry@dot.gov; Duffey, Michael P. EOP/OMB (b)(6); Eisenberg, John A. EOP/WHO (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Grogan, Joseph J. EOP/WHO (b)(6); Hemme, Jake W. EOP/NSC (b)(6); Hennessey, Millicent S. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kan, Derek T. EOP/OMB (b)(6); Kenneth.p.rapuano.civ (b)(6); Liddell, Christopher P. EOP/WHO (b)(6); Miller, Julie L. EOP/OMB (b)(6); Mulvaney, Mick M. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Robert.g.saleses.civ (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Pottinger, Matthew F. EOP/WHO (b)(6); Riggs, Charlotte R. EOP/WHO (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ruggiero, Anthony J. EOP/NSC (b)(6); Scher, Adam A. EOP/OMB (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulliyot, John L. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Woolfolk, Jon J. EOP/OVP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; DL OVP NSA EXECSEC (b)(6); Bauer, Zachary C. EOP/OVP (b)(6); Moore, Caroline E. EOP/WHO (b)(6); Galkowski, James J. EOP/WHO (b)(6); OVPSchedule (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Troye, Olivia EOP/NSC (b)(6); Loyetcj (b)(6); HattinghEF (b)(6); NanavattyKB (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Cavanaugh, Brian J. EOP/NSC (b)(6)  
**CC:** Thurston, Eliza C. EOP/OVP (b)(6); Scully, Bethany S. EOP/OVP (b)(6); Stickles, Brendan R. EOP/OVP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; McBride, Emily J. EOP/WHO (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative



---

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Paz, Brooke L.  
EOP/WHO (b)(6)

**Subject:** COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants + Materials + Seating Chart  
**Attachments:** UPDATED - Supply Chain Options - N95 (PPE).docx; VPOTUS COVID19 - Seating Chart.pdf; Task Force Agenda 2.29.2020 1000 (005).docx; 02.29.2020 TAB C Travel Restrictions Options Grid.jpg  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Busy

All,

There will be a **Coronavirus Task Force Principal's Meeting** at **10:00am** in the **White House Situation Room**. Agenda and read-ahead materials attached.

**Please see attached seating chart for approved attendees.**

Thank you,

**Natalie Hurst**

Executive Assistant to the Chief of Staff

The Office of the Vice President

(b)(6)

**From:** Short, Marc T. EOP/OVP; (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP; (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Ferro, Phil J. EOP/NSC; (b)(6); AMA2@HHS.GOV; as2ktd; (b)(6); BiegunSE; (b)(6); Devin.O'Malley@treasury.gov; Blair, Robert B. EOP/WHO; (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hodgson, Christopher M. EOP/OVP; (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO; (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC; (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO; (b)(6); donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC; (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Hoelscher, Douglas L. EOP/WHO; (b)(6); Jacqueline.Colli@va.gov; Kenneth.p.rapuano.civ; (b)(6); Robert.g.salesses.civ; (b)(6); Pataki, Tim A. EOP/WHO; (b)(6); Pottinger, Matthew F. EOP/WHO; (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9d983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulyyot, John L. EOP/NSC; (b)(6); Williams, Michael B. EOP/WHO; (b)(6); Wilson, John Mark M. EOP/NSC; (b)(6); Lin, Merry S. EOP/WHO; (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; WILLIAM.FERRARA; (b)(6); Loyetcj; (b)(6); HattinghEF; (b)(6); NanavattyKE; (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]

**Subject:** Coronavirus Task Force Principals Meeting - 10:00am  
**Location:** WHSR JFK

**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Busy

-----Original Appointment-----

**From:** Short, Marc T. EOP/OVP <(b)(6)>  
**Sent:** Friday, February 28, 2020 5:23 PM  
**To:** Short, Marc T. EOP/OVP; Ferro, Phil J. EOP/NSC; AMA2@HHS.GOV; as2ktd; (b)(6); BiegunSE; (b)(6); Devin.O'Malley@treasury.gov; Blair, Robert B. EOP/WHO; Harrison, Brian (OS); Hodgson, Christopher M. EOP/OVP; Amie Kalsbeek (DOT); Butterfield, Nicholas W. EOP/WHO; Cetron, Martin (CDC); Chafin, Kelly B. EOP/NSC; Conrad, Patricia L (NIH); Davis, May M. EOP/WHO; donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC; Fauci, Anthony S (NIH); Hoelscher, Douglas L. EOP/WHO; Jacqueline.Colli@va.gov; Kenneth.p.rapuano.civ; (b)(6); Robert.g.salesses.civ; (b)(6); Pataki, Tim A. EOP/WHO; Pottinger, Matthew F. EOP/WHO; Redfield, Robert R (CDC); Kadlec, Robert P (OS); Joel.Szabat@dot.gov; Tignor, Beth (OS); Ulyyot, John L. EOP/NSC; Williams, Michael B. EOP/WHO; Wilson, John Mark M. EOP/NSC; Lin, Merry S. EOP/WHO; Zachary.McEntee@treasury.gov; Adams, Jerome (OS);

WILLIAM.FERRARA; (b)(6); Loyetcj; (b)(6); HattinghEi; (b)(6); NanavattyKB; (b)(6); Sheehy, Janice

**Subject:** Coronavirus Task Force Principals Meeting - 10:00am

**When:** Saturday, February 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** WHSR JFK

All,

There will be a **Coronavirus Task Force Principal's Meeting** tomorrow morning at **10:00am in the White House Situation Room**. More details and an agenda will be forthcoming.

**If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting.**

**WAVES Link:** (b)(6)

Participants:

Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

**Natalie Hurst**

Executive Assistant to the Chief of Staff

The Office of the Vice President

(b)(6)

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Shellooe, Ryan P. EOP/NSC (b)(6)  
Ferro, Phil J. EOP/NSC (b)(6); Hurst, Natalie R. EOP/OVP (b)(6)  
AMA2@HHS.GOV; as2kctc (b)(6); BiegunSE (b)(6); Bigley, Mark C. EOP/OMB  
(b)(6); Devin.O'Malley@treasury.gov; Grisham, Stephanie A. EOP/WHO  
(b)(6); Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian  
(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Miller, Katie R. EOP/OVP  
(b)(6); Hodgson, Christopher M. EOP/OVP (b)(6); Amie  
Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO  
(b)(6); Campana, Alexandra D. EOP/WHO (b)(6)  
Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B.  
EOP/NSC (b)(6); Conant, Ann M. EOP/OMB (b)(6); Conley, Sean P.  
CDR USN WHMO/WHMU (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp];  
Davis, May M. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL  
Chief of Staff Office (b)(6); donna.oberry@dot.gov; Duffey, Michael P. EOP/OMB  
(b)(6); Eisenberg, John A. EOP/WHO (b)(6); Fabina, Lauren  
C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-];  
Grogan, Joseph J. EOP/WHO (b)(6); Hemme, Jake W. EOP/NSC  
(b)(6); Hennessey, Millicent S. EOP/NSC (b)(6); Hoelscher,  
Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kan, Derek T. EOP/OMB  
(b)(6); Kenneth.p.rapuano.civ (b)(6); Liddell, Christopher P. EOP/WHO  
(b)(6); Miller, Julie L. EOP/OMB (b)(6); Mulvaney, Mick M.  
EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6)  
Robert.g.saleses.civ (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Pottinger, Matthew F.  
EOP/WHC (b)(6); Riggs, Charlotte R. EOP/WHO (b)(6); Redfield,  
Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ruggiero, Anthony J.  
EOP/NSC (b)(6); Scher, Adam A. EOP/OMB (b)(6); Sinclair,  
Michael R. EOP/NSC (b)(6); Joel.Szabat@dot.gov; Tignor, Beth (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulyot, John L. EOP/NSC  
(b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John  
Mark M. EOP/NSC (b)(6); Woolfolk, Jon J. EOP/OVP (b)(6); Lin,  
Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; DL OVP NSA EXECSEC  
(b)(6); WILLIAM.FERRARA (b)(6); Bauer, Zachary C. EOP/OVP  
(b)(6); Moore, Caroline E. EOP/WHO (b)(6); Galkowski, James  
J. EOP/WHO (b)(6); OVPSchedule (b)(6); Droegemeier, Kelvin  
K. EOP/OSTP (b)(6); Baum, Kristina R. EOP/OSTP (b)(6)  
Troye, Olivia EOP/NSC (b)(6); Loyetcj (b)(6); HattinghEF (b)(6)  
NanavattyKB (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Cavanaugh, Brian J.  
EOP/NSC (b)(6)  
**CC:** Thurston, Eliza C. EOP/OVP (b)(6); Scully, Bethany S. EOP/OVP  
(b)(6); Stickles, Brendan R. EOP/OVP (b)(6); Hahn, Stephen  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; McBride, Emily J.  
EOP/WHO (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Paz, Brooke L.  
EOP/WHO (b)(6)

---

**Subject:** COVID-19 Taskforce Principals Meeting - 10:00am - Agenda + Participants  
**Attachments:** Task Force Agenda 2.29.2020 1000.docx; UPDATED - Supply Chain Options - N95 (PPE).docx  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Tentative

All,

There will be a **Coronavirus Task Force Principal's Meeting** tomorrow morning at **10:00am in the White House Situation Room**. Agenda and read-ahead materials attached.

**If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting. (Closed)**

**WAVES Link:** (b)(6)

Participants:

Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Kenneth P. Rapuano, Assistant Secretary of Defense for Homeland Defense and Global Security

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Dr. Stephen M. Hahn, Commissioner of Food and Drug Administration (FDA)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Assistant to the President, Deputy Counsel for National Security Affairs, and National Security Council Legal Advisor

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Director of Legislative Affairs, Office of the Vice President

**Natalie Hurst**

Executive Assistant to the Chief of Staff

The Office of the Vice President

(b)(6)

**From:** Short, Marc T. EOP/OVP (b)(6)  
**Sent:** 2/28/2020 5:29:57 PM  
**To:** Short, Marc T. EOP/OVP (b)(6); Ferro, Phil J. EOP/NSC (b)(6); AMA2@HHS.GOV; as2kctc (b)(6); BiegunSE (b)(6); Devin.O'Malley@treasury.gov; Blair, Robert B. EOP/WHO (b)(6); Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hodgson, Christopher M. EOP/OVP (b)(6); Amie Kalsbeek (DOT) [amie.kalsbeek@dot.gov]; Butterfield, Nicholas W. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Chafin, Kelly B. EOP/NSC (b)(6); Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Davis, May M. EOP/WHO (b)(6); donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Hoelscher, Douglas L. EOP/WHO (b)(6); Jacqueline.Colli@va.gov; Kenneth.p.rapuano.civ (b)(6); Robert.g.salesses.civ (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Pottinger, Matthew F. EOP/WHO (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Joel.Szabat@dot.gov; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Ulyyot, John L. EOP/NSC (b)(6); Williams, Michael B. EOP/WHO (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Lin, Merry S. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; WILLIAM.FERRARA (b)(6); Loyetc (b)(6); HattinghEF (b)(6); NanavattyKE (b)(6); Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Coronavirus Task Force Principals Meeting - 10:00am  
**Location:** WHSR JFK  
**Start:** 2/29/2020 10:00:00 AM  
**End:** 2/29/2020 11:00:00 AM  
**Show Time As:** Busy

All,

There will be a **Coronavirus Task Force Principal's Meeting** tomorrow morning at **10:00am in the White House Situation Room**. More details and an agenda will be forthcoming.

If you do not have **White House credentials**, please fill out the **WAVES Link** before **9:00pm** tonight in order to be cleared onto **The Complex** ahead of tomorrow morning's meeting.

**WAVES Link:** (b)(6)

Participants:



Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Kenneth P. Rapuano, Assistant Secretary of Defense for Homeland Defense and Global Security

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

**Natalie Hurst**

Executive Assistant to the Chief of Staff

The Office of the Vice President

(b)(6)

**From:** Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]  
**Sent:** 2/28/2020 5:38:25 PM  
**To:** Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwen]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]

**Subject:** HHS COVID-19 Response - alignment of OPDIV/STAFFDIV Efforts  
**Location:** Thomas P. O'Neill Federal Building - 200 C Street SW | Washington, DC 20515  
**Start:** 3/4/2020 9:00:00 AM  
**End:** 3/4/2020 10:15:00 AM  
**Show Time As:** Tentative  
  
**Recurrence:** (none)

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to **(b)(6)** no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)

- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec  
ASPR

POC:

**Cicely L. Waters**

Director, Office of External Affairs

Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

200 C St, SW Washington, D.C. 20201

(o) 202-205-0714 (m) **(b)(6)**

[cicely.waters@hhs.gov](mailto:cicely.waters@hhs.gov)

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 2/28/2020 5:44:45 PM  
**To:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]  
**Subject:** Re: Coronavirus Task Force Principals Meeting - 10:00am

Nope. He should be there. Thanks!

Sent from my iPhone

On Feb 28, 2020, at 5:40 PM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

I can ask Marc's assistant – will let you know.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, February 28, 2020 5:39 PM  
**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>  
**Subject:** Re: Coronavirus Task Force Principals Meeting - 10:00am

(b)(6) Is this mandatory?

Sent from my iPhone

On Feb 28, 2020, at 5:29 PM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

Hi, this meeting invite just came in for TOMORROW, 10:00-11:00 am, White House Situation Room. I'll forward this to SH's calendar now, as well as get WAVES submitted. Marc Short, CoS to VP, now has SH's cell and email address. Thanks! -j

-----Original Appointment-----

**From:** Natalie.R.Hurst (b)(6) <Natalie.R.Hurst (b)(6)> **On Behalf Of** Short, Marc T. EOP/OVP  
**Sent:** Friday, February 28, 2020 5:25 PM  
**To:** Ferro, Phil J. EOP/NSC; AMA2@HHS.GOV; as2ktd (b)(6); BiegunSE (b)(6); Devin.O'Malley (b)(6); Blair, Robert B. EOP/WHO; Harrison, Brian (OS); Hodgson, Christopher M. EOP/OVP; Amie Kalsbeek (DOT); Butterfield, Nicholas W. EOP/WHO; Cetron, Martin (CDC); Chafin, Kelly B. EOP/NSC; Conrad, Patricia L (NIH); Davis, May M. EOP/WHO; donna.oberry@dot.gov; Fabina, Lauren C. EOP/NSC; Fauci, Anthony S (NIH); Hoelscher, Douglas L. EOP/WHO; Jacqueline.Collins@va.gov; Kenneth.p.rapuanociv (b)(6); Robert.g.salesses.civ (b)(6); Pataki, Tim A. EOP/WHO; Pottinger, Matthew F. EOP/WHO; Redfield, Robert R (CDC); Kadlec, Robert P (OS); Joel.Szabat@dot.gov;

Tignor, Beth (OS); Ulyot, John L. EOP/NSC; Williams, Michael B. EOP/WHO; Wilson, John Mark M. EOP/NSC; Lin, Merry S. EOP/WHO; Zachary, McEnte (b)(6); Adams, Jerome (OS); WILLIAM.FERRARA (b)(6); Loyetcj (b)(6); HattinghEF (b)(6); NanavattyKB (b)(6); Sheehy, Janice

**Subject:** Coronavirus Task Force Principals Meeting - 10:00am

**When:** Saturday, February 29, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** WHSR JFK

All,

There will be a **Coronavirus Task Force Principal's Meeting** tomorrow morning at **10:00am in the White House Situation Room**. More details and an agenda will be forthcoming.

**If you do not have White House credentials, please fill out the WAVES Link before 9:00pm tonight in order to be cleared onto The Complex ahead of tomorrow morning's meeting.**

**WAVES Link:** (b)(6)

Participants:

Vice President Pence

Marc Short, Chief of Staff to the Vice President

Mick Mulvaney, Chief of Staff to the President

Secretary Alex Azar, Department of Health and Human Services

Secretary Steven Mnuchin, Secretary of the Treasury

LTG Joseph Kellogg, Assistant to the President and National Security Advisor to the Vice President

Larry Kudlow, Assistant to the President for Economic Policy & Director of the National Economic Council

Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health

Dr. Jerome Adams, Surgeon General of the United States

Deputy Secretary Stephen Biegun, Department of State

Dr. Kelvin Droegemeier, Director, Office of Science and Technology Policy (OSTP)

Ken Cuccinelli, Acting Deputy Secretary, Department of Homeland Security

Joel Szabat, Acting Under Secretary for Policy, Department of Transportation

Matthew Pottinger, Assistant to the President and Deputy National Security Advisor

Rob Blair, Assistant to the President and Senior Advisor to the Chief of Staff

Joseph Grogan, Assistant to the President and Director of the Domestic Policy Council

William Ferrara, Executive Assistant Commissioner (CBP)

Christopher Liddell, Assistant to the President and Deputy Chief of Staff for Policy Coordination

Derek Kan, Executive Associate Director, Office of Management and Budget

Dr. Robert Kadlec, HHS, Assistant Secretary for Preparedness and Response (ASPR)

John Eisenberg, Deputy Council to the President for National Security Affairs & Legislative Advisor to the National Security Council

Olivia Troye, Special Advisor to the Vice President for Homeland Security

Anthony Ruggiero, National Security Council, Special Assistant to President and Senior Director for Counterproliferation and Biodefense

Katie Miller, Press Secretary to the Vice President

Chris Hodgson, Deputy Director of Legislative Affairs, Office of the Vice President

**Natalie Hurst**

Executive Assistant to the Chief of Staff  
The Office of the Vice President

**(b)(6)**



---

**From:** Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]  
**Sent:** 2/28/2020 5:46:42 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**Subject:** FW: Updated TPs  
**Attachments:** SH House Update 2.28.20 925pm.docx

Moving to the top of your inbox for tomorrow. A reminder that I think you moved the order around for this morning's briefing.

---

**From:** Gross, Karas  
**Sent:** Thursday, February 27, 2020 9:34 PM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Subject:** Updated TPs

(b)(5)

Thanks for your patience on these changes and let us know if you have questions.

Karas

---

**From:** McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]  
**Sent:** 2/28/2020 6:24:41 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**Subject:** info for Merkley call  
**Attachments:** 2020 0228 Hahn Merkley Coronavirus meeting.docx

Commissioner-

Attached is a detailed memo for the Merkley call. Below are two of the specific areas we discussed that I pulled out for you.

(b)(5)

**(b)(5)**

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 2/28/2020 6:36:18 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts

Great, thanks!

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, February 28, 2020 6:35 PM  
**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts

SH does not need to attend this. Not principal level.

Sent from my iPhone

On Feb 28, 2020, at 5:51 PM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

Hi, please see below the invite (and the information being requested by noon on Monday) that just came in for Wednesday morning. This conflicts with SH's keynote at the ACLA Annual Meeting.

-----Original Appointment-----

**From:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>  
**Sent:** Friday, February 28, 2020 5:38 PM  
**To:** Kadlec, Robert (OS/ASPR/IO); Ford-Barnes, Arwenithia (OS); Waters, Cicely (OS); Shuy, Bryan (OS); Callahan, Victoria (OS); Moreno, Rafael (OS); Trueman, Laura (OS); Rowell, Scott (OS); Bird, Catherine (OS); Moughalian, Jen C (OS); Arbes, Sarah C (OS); Murphy, Ryan (OS); Destro, Brenda (OS); Giroir, Brett (OS); Severino, Roger (OS); Grigsby, Garrett G (OS); Kerr, Lawrence (OS); Charrow, Robert (OS); Grimm, Christi A (OIG); Griswold, Nancy J (OS); Op Divs; Johnson, Lynn (ACF); Robertson, Lance (ACL); Khanna, Gopal (AHRQ); Redfield, Robert R (CDC); Verma, Seema (CMS); Saxon, Bobby (CMS); Hahn, Stephen; Hinton, Denise; Engels, Thomas J (HRSA); Weahkee, Michael (IHS); McCollum, Jeffrey (IHS); Frazier, Francis (IHS); Collins, Francis S (NIH); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); McCance-Katz, Elinore (SAMHSA); Krohmer, Jon (dot.gov)  
**Subject:** HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts  
**When:** Wednesday, March 4, 2020 9:00 AM-10:15 AM (UTC-05:00) Eastern Time (US & Canada).  
**Where:** Thomas P. O'Neill Federal Building - 200 C Street SW | Washington, DC 20515

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to **(b)(6)** no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec  
ASPR

POC:

**Cicely L. Waters**

Director, Office of External Affairs

Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

200 C St, SW Washington, D.C. 20201

(o) 202-205-0714 (m) **(b)(6)**

cicely.waters@hhs.gov

---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 2/28/2020 6:51:08 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Subject:** Accepted: COVID-19 Agency Executive Group Meeting  
**Location:** 1-877-465-7975, code (b)(6) or COO Conference Room (WO2/3305)  
**Start:** 3/2/2020 9:15:00 AM  
**End:** 3/2/2020 9:30:00 AM  
  
**Recurrence:** (none)

**From:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Sent:** 2/28/2020 6:54:42 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSE]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Solberg, Tim  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Rebello, Heidi  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Clarke, Mary Beth  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Yiannas, Frank  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Finnen, April  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KMO8]; Lynch, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccamo, Stephanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; 2019-nCoV FDA IMG  
 Planning [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Chiverton, Evan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=664891126c2f4b36a17ff06fc18ad73d-Evan.Chiver]; Measer, Gregory  
 [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Boon, Caitlin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group



(FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Aldridge, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f7761ef82074a45a6a58ac539b3dbb5-Megan.McCur]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Gutierrez, Sacha [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8490d020e45245b48335435bd64bd384-Sacha.Gutie]; Demers, Donald E [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee9abcfa1b9a4d2a9222bd5ebb733faf-DDEMERS]; Pillai, Segaran [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5e546783d4445fa315d858e0c92d47-Segaran.Pil]; Stone, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Schweitzer, Roxanne K [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Huttenlocker, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Hussey, Deirdre [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barfell, Glenda F [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Domanski, Jeffrey [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebf0a50f6cd4d7f9-Jeffrey.Dom]; Cason, Winona [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3434073fc4cc4b578c59ca60a5da91f8-Winona.Caso]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Johanson, Elaine [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Mignone, Alfred [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]  
Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dccc89b861b673-JOS]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Brubach, April [/o=ExchangeLabs/ou=Exchange Administrative Group

CC:

---

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dae6b9c3a9f04ea9b63a2aeabd21ed6f-April.Bruba]; Frasca, Dominic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5975945e67674e19b4f4a02025c5b6b5-Dominic.Fra]

**Subject:** COVID-19 AEG Weekend Check-in

**Attachments:** COVID-19 Agency Executive Group meeting; COVID-19 Agency Executive Group Weekend Check-in; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Agenda\_COVID19 Meetings\_24MAR2020\_rev (002).doc; Untitled Attachment; Untitled Attachment; Untitled Attachment

**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)

**Start:** 3/21/2020 3:00:00 PM

**End:** 3/21/2020 3:30:00 PM

**Show Time As:** Busy

**Recurrence:** Weekly  
every Sunday and Saturday from 3:00 PM to 3:30 PM

**Required Attendees:** Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Zeller, Mitchell; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Rebello, Heidi; Clarke, Mary Beth; Yiannas, Frank; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccomo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; McWilliams, Carly; 2019-nCoV FDA IMG Planning; Chiverton, Evan; Measer, Gregory; Boon, Caitlin; Edmonds, Amanda; Felberbaum, Michael; Dooren, Jennifer; Franklin, Joseph; Slikker, William; Courtney, Brooke; Sadove, Elizabeth; Aldridge, Megan; Barth, Janelle; Gutierrez, Sacha; Demers, Donald E; Pillai, Segaran; Stone, Eric; Schweitzer, Roxanne K; Huttenlocker, Denise; Hussey, Deirdre; Barfell, Glenda F; Domanski, Jeffrey; Cason, Winona; McBride, Maren; Johanson, Elaine; Raghuvanshi, Rakesh; Klimczak, Katherine; Mignone, Alfred; Block, Molly

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities.

AEG representatives from Centers/Offices will provide **brief** updates on key issues and activities on their respective areas, as applicable.

---

**From:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]  
**Sent:** 2/28/2020 6:54:42 PM  
**To:** Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cason, Winona [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3434073fc4cc4b578c59ca60a5da91f8-Winona.Caso]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Musser, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7749e25df5f499eb98f341654fd2470-SMUSSER]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Throckmorton, Douglas

C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Zeller, Mitchell  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Solberg, Tim  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b745ab0b019f40d5b6ee396523a713ad-Timothy.Sol]; Keller, Melanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Schwartz, Suzanne  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Tyler, James  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Beach, Carter  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cc25b1b821d4c55a7a05eb0fdd5d338-Carter.Beac]; Cavazzoni, Patrizia  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Rebello, Heidi  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Clarke, Mary Beth  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Yiannas, Frank  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Tantillo, Andrew  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Malais, Tanya  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]; Finnen, April  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Agler, Heather L  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Ricci, Linda J  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; O'Callaghan, Kathryn  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ef8cc4dd874b10a04ea7834abbfb1e-KM08]; Lynch, Sarah  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Walsh, Sandy  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Bess, Demetrice  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]; Cho, David S (CBER)  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Caccamo, Stephanie  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Ross, Bruce  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Torres-Rivera, Sahra  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=250b39db620a435598daa9874d395563-Sahra.Torre]; Rom, Colin  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; 2019-nCoV FDA IMG  
 Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Chiverton, Evan  
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=664891126c2f4b36a17ff06fc18ad73d-Evan.Chiver]; Measer, Gregory

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Boon, Caitlin  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Edmonds, Amanda  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Felberbaum, Michael  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Dooren, Jennifer  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Franklin, Joseph  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Slikker, William  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Courtney, Brooke  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Sadove, Elizabeth  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Aldridge, Megan  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f7761ef82074a45a6a58ac539b3dbb5-Megan.McCur]; Barth, Janelle  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Gutierrez, Sacha  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8490d020e45245b48335435bd64bd384-Sacha.Gutie]; Demers, Donald E  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee9abcfa1b9a4d2a9222bd5ebb733faf-DDEMERS]; Pillai, Segaran  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5e546783d4445fa315d858e0c92d47-Segaran.Pil]; Stone, Eric  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5799d336f4c142aca71a655e4184d6bd-Eric.Stone]; Schweitzer, Roxanne K  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292135d254924252958e25cc5a63b079-RSCHWEIT]; Huttenlocker, Denise  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65254282fa6a4e138f506f96cfe9049c-Denise.Hutt]; Hussey, Deirdre  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; Barfell, Glenda F  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33b220e98ac9456eb32888261156f400-GBARFELL]; Domanski, Jeffrey  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ed00c0aa83794cbebf0a50f6cd4d7f9-Jeffrey.Dom]; McBride, Maren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Johanson, Elaine  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]; Raghuwanshi, Rakesh  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Klimczak, Katherine  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Mignone, Alfred  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]  
CC: Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dcce89b861b673-JOS]; Roth, Lauren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Schiller, Lowell  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Brubach, April  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dae6b9c3a9f04ea9b63a2aeabd21ed6f-April.Bruba]

---

**Subject:** Copy: COVID-19 AEG Weekend Check-in  
**Attachments:** Agenda\_COVID19 Meetings\_23MAR2020\_rev (002).doc; Agenda\_COVID19 Meetings\_23MAR2020\_rev (002).doc  
**Location:** CALL-IN ONLY: 1-877-465-7975, code: (b)(6)

**Start:** 3/29/2020 1:30:00 PM  
**End:** 3/29/2020 2:00:00 PM  
**Show Time As:** Busy

**Recurrence:** (none)

**Required Attendees:** Cason, Winona; Hahn, Stephen; Lenihan, Keagan; Amin, Stacy; Sigg, Jim; Hebert, Angelique A.; Abernethy, Amy; Tootle, William; Carter, Lionel; Marks, Peter; Farley, John; Shuren, Jeff; Solomon, Steven M; Forfa, Tracey; Rogers, Michael; McMeekin, Judith; Abdoo, Mark; Anderson, Erika; Branch, Tiffany; Tse, Tania; Caliguiri, Laura; Raza, Mark; Mair, Michael; Mayne, Susan; Musser, Steven M; Shah, Anand; Throckmorton, Douglas C; Zeller, Mitchell; Solberg, Tim; Keller, Melanie; Schwartz, Suzanne; Tyler, James; Beach, Carter; Cavazzoni, Patrizia; Rebello, Heidi; Clarke, Mary Beth; Yiannas, Frank; Tantillo, Andrew; Gross, Karas; Malais, Tanya; Finnen, April; Agler, Heather L; Ricci, Linda J; O'Callaghan, Kathryn; Lynch, Sarah; Walsh, Sandy; Bess, Demetrice; Cho, David S (CBER); Caccomo, Stephanie; Ross, Bruce; Torres-Rivera, Sahra; Rom, Colin; McWilliams, Carly; 2019-nCoV FDA IMG Planning; Chiverton, Evan; Measer, Gregory; Boon, Caitlin; Edmonds, Amanda; Felberbaum, Michael; Dooren, Jennifer; Franklin, Joseph; Slikker, William; Courtney, Brooke; Sadove, Elizabeth; Aldridge, Megan; Barth, Janelle; Gutierrez, Sacha; Demers, Donald E; Pillai, Segaran; Stone, Eric; Schweitzer, Roxanne K; Huttenlocker, Denise; Hussey, Deirdre; Barfell, Glenda F; Domanski, Jeffrey; McBride, Maren; Johanson, Elaine; Raghuwanshi, Rakesh; Klimczak, Katherine; Mignone, Alfred

Weekend AEG check-in meetings to provide high-level updates on cross-agency top-level issues and activities. AEG representatives from Centers/Offices will provide **brief** updates on key issues and activities on their respective areas, as applicable.