From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/24/2020 5:03:44 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Dr. Hahn media/scheduling

Location: SC to call EM

Start: 8/25/2020 11:00:00 AM **End**: 8/25/2020 11:30:00 AM

Show Time As: Busy

Required Miller, Emily

Attendees:

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/24/2020 2:24:20 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Felberbaum, Michael

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Kimberly, Brad

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: SC OOO

Start: 8/27/2020 1:00:00 PM **End**: 8/27/2020 5:00:00 PM

Show Time As: Free

Importance: High

Required Hatch, Shannon; Felberbaum, Michael; Kimberly, Brad

Attendees:

FDA Office of Media Affairs [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA68DCACB6414BFCB486F469C04BC5F1-FDAOFFICEOF]

Sent: 8/24/2020 2:16:45 PM

To: FDA Office of Media Affairs [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba68dcacb6414bfcb486f469c04bc5f1-FDAOfficeof]; Herring, Kenneth (Lee)

[/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=24da18002bf64ae788c452b94f4bb12a-Kenneth.Her]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

CC: Thompson, Twyla [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c51af6601aa74a1c9c63391384a41230-THOMPSONT]

Subject: Canceled: OMA Check in

Location: or WO 32/5344 WebEx 210-795-0506; (b) (6)

Start: 2/5/2020 3:30:00 PM End: 2/5/2020 4:00:00 PM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Wednesday from 3:30 PM to 4:00 PM

Required Arnold, Nathan; Caccomo, Stephanie; Capobianco, Abigail; Cassell, Peter; Felberbaum, Michael; Garcia, Megan; Attendees: Hatch, Shannon; Hunt, Alison; Jarrell, Kristin; Kahn, Jeremy; Kimberly, Brad; Manchester, Brittney; McCarthy, Lauren-

> Jei; McKinney, James; McSeveney, Megan; Mueller, Nicole; O'Keefe, Lindsey; Rabin, Tara G.; Rhodes, Courtney; Richards, Monique; Sanchez-Contreras, Gloria; Spaulding, Emma; Taiwo, Wumi; Tantibanchachai, Chanapa; Thorpe,

Valarie; Turney, Amanda

Agenda for Wednesdays:

- Team Updates/Team-Building
- COVID-19 Updates, Process/Staffing Feedback
- Team Nags & Flags

New dial-in information below.

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: Dickinson, Elizabeth (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=05CB143D66ED470EBE4DBA5C54A88074-EDICKINS]

Sent: 8/24/2020 2:47:14 PM

To: Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Mednick, David

[David.Mednick@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]

Subject: OCC Briefing Location: Conf. Call

Start: 8/27/2020 1:00:00 PM **End**: 8/27/2020 1:30:00 PM

Show Time As: Busy

Required Miller, Emily; Mednick, David; Raza, Mark

Attendees:

- Do not delete or change any of the following text. --

To join the audio portion of the Personal Conference meeting

Meeting password: (b) (6)

Join meeting

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

Attendee access code: (b) (6)

* US Toll should only be used if the primary number does not work.

Need help? Go to http://help.webex.com

From: FDA Office of Media Affairs [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIF

Sent: 8/24/2020 2:16:04 PM

To: FDA Office of Media Affairs [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=

(Lee) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24da18002bf64ae788

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664

Subject: Canceled: OMA Check-In

Location: +1-877-465-7975, ID: (b) (6) (WO 32/5344)

 Start:
 2/11/2019 3:00:00 PM

 End:
 2/11/2019 3:30:00 PM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Monday from 3:00 PM to 3:30 PM

Required Attendees: Arnold, Nathan; Caccomo, Stephanie; Capobianco, Abigail; Cassell, Peter; Felberbaum, Michael; Garcia, Megan; Hatch, Sha

McCarthy, Lauren-Jei; McKinney, James; McSeveney, Megan; Mueller, Nicole; O'Keefe, Lindsey; Rabin, Tara G.; Rhodes, Co

Emma; Taiwo, Wumi; Tantibanchachai, Chanapa; Thorpe, Valarie; Turney, Amanda

Agenda for Mondays:

Team/operations updates

Forecast & COVID-19 Tracker review, timing updates

Nags & Flags

You're invited to join this Webex meeting.

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Every Monday, from Monday, June 29, 2020, to no end date 3:00 pm | Eastern Daylight Time (New York, GMT-04:00) | 30 mins

Join meeting

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

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]

Sent: 8/24/2020 11:31:52 AM

To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Zeta, Lowell

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

CC: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]

Subject: Canceled: Int Call - Introduction: Emily Miller / Lowell Zeta / Anand Shah

Location: 8774657975,,(b) (6)

Start: 8/25/2020 5:00:00 PM **End**: 8/25/2020 5:15:00 PM

Show Time As: Free

Required Zeta, Lowell; Miller, Emily

Attendees:

Quick discussion about PREPP Comms.

Please see new time and contact Jenna for any issues. Thank you.

-- 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

Tap to join from a mobile device (attendees only)

210-795-0506, (b) (6) US Toll 877-465-7975, (b) (6) US Toll Free

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

Need help? Go to http://help.webex.com		

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/21/2020 5:06:32 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, 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]

Subject: Canceled: [PENDING OMA RESPONSE] MEDIA HOLD: Sinclair Media (POC: Stephanie Caccomo)

Location: HHS Studio

Start: 8/28/2020 11:00:00 AM End: 8/28/2020 1:00:00 PM

Show Time As: Free

Importance: High

Required Miller, Emily; Stephanie Caccomo; Felberbaum, Michael

Attendees:

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]

Sent: 8/24/2020 11:31:04 AM

To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Hahn, Stephen

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0a fac Ocfa 3 c 4b 98913833e 38a 036e 9f-Stephen. Hah]; Abernethy, Amy and the state of the state

[/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]; 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]; Tobias, Lindsay

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Zeta, Lowell

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]; Amin, Stacy

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Beckerman, Peter

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=182e3800db204bb88cf3863bad5259b6-PBeckerm]; Schifter, Karen

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e053263245384529be8a78174412d8f4-KSchifte]; Abram, Anna

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Rom, Colin

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schiller, Lowell

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Tantillo, Andrew

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Roth, Lauren

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; McBride, Maren

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Yiannas, Frank

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Boon, Caitlin

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Jenkins, Yolanda

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f074311e73aa4061a2dfee3827751964-Yolanda.Jen]; Mayne, Susan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Kavanaugh, Claudine

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Stearn, Douglas

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Carroll, Laura

[/o=ExchangeLabs/ou=Exchange Administrative Group

 $(FYDIBOHF23SPDLT)/cn=Recipients/cn=9cb6e346de33480889c94630f0a6ea55-Laura. Carro]; \ Kux, \ Leslie \$

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; Dooren, Jennifer

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Choiniere, Conrad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=053706355e7e41179c63737c416451fb-CChoinie]; Balentine, Douglas

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=6b28f8a3dd3e4c13ad33a74686846bcd-Douglas.Bal]; Carey, Emily Rose

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]; Taylor, Paige

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2f46091afaf2483abb72d8db96066f15-PTaylor]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Rebello, Heidi

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; McKinnon, Robin

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=bd27415bf7ea4a9da98b7b6e6da43ad3-Robin.McKin]

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]

Subject: Canceled: Canceled, to be Rescheduled - New Date/Time Rescheduled: Commissioner Briefing: Nutrition Innovation

Strategy

Attachments: BriefingMemoNutrition_Aug2020.Updated.docx; Tab A - Nutrition Innovation Strategy Briefing.docx; Tab B -

Nutrition Innovation Strategy.docx; NISCommissionerHahnBriefing Aug2020 CLEAN.pptx

Location: Dial in: 1-866-507-5707 Passcode: (b) (6)

Start: 8/25/2020 10:00:00 AM **End**: 8/25/2020 11:00:00 AM

Show Time As: Free

Importance: High

Required Hahn, Stephen (SH1@fda.hhs.gov); Abernethy, Amy; Franklin, Joseph; Shah, Anand; Lenihan, Keagan; Tobias,

Attendees: Lindsay; Zeta, Lowell; Amin, Stacy; Beckerman, Peter; Schifter, Karen; Abram, Anna; Anderson, Erika; Rom, Colin;

Schiller, Lowell; Tantillo, Andrew; Roth, Lauren; Wagner, John; McBride, Maren; Yiannas, Frank; Boon, Caitlin; Jenkins, Yolanda; Mayne, Susan; Kavanaugh, Claudine; Stearn, Douglas; Carroll, Laura; Kux, Leslie; Dooren, Jennifer; Choiniere, Conrad; Balentine, Douglas; Carey, Emily Rose; Taylor, Paige; Miller, Emily; Rebello, Heidi; McKinnon,

Robin

8/25 - Unfortunately, the Commissioner is no longer able to join this briefing at 10 am – but we are working to reschedule for either later in the day or very soon after.

Update – Please note New Briefing Date and Time.

(8/24) Update - Briefing is cancelled but will be rescheduled for a later date.

See briefing materials attached.

A briefing for the Commissioner to discuss Nutrition Innovation Strategy has been re-scheduled for Tuesday, August 25, from 10:00 AM – 11:00 AM.

New Date: Tuesday, August 25, 2020 **New Time:** 10:00 AM – 11:00 AM

Note: Reminder to please be sure to mute your phone unless you are speaking.

FDA-OC- OMA COMS Aug20P1

Call-in Information:

Dial in: 1-866-507-5707 Passcode: (b) (6)

Please do not forward this invitation. If additional staff need to attend, please let me know. OC/Office of the Executive Secretariat Contact: Yolanda K. Jenkins, 240-447-1524

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/24/2020 12:19:26 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; 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]

Subject: Canceled: Media Hold (TBC)
Location: Details TBP (POC: Emily Miller)

Start: 8/25/2020 8:12:00 AM **End**: 8/25/2020 8:17:00 AM

Show Time As: Free

Importance: High

Required Miller, Emily; Wagner, John; Felberbaum, Michael; Stephanie Caccomo

Attendees:

From: Broderick, Brianna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C2403F4ADAE453CA6EFD28044DDEF37-BRODERICKB)

Sent: 8/24/2020 10:37:56 AM

To: Broderick, Brianna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2403f4adae453ca6efd28044ddef37-BRODERICKB]; Carter, Lionel

[Lionel.Carter@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Thrash, Karl

[Karl.Thrash@fda.hhs.gov]; Palmer, Kelly [Kelly.Palmer@fda.hhs.gov]

Subject: Rescheduled - Physical Security Briefing

Location: Webex

Start: 8/24/2020 11:30:00 AM **End**: 8/24/2020 12:00:00 PM

Show Time As: Busy Importance: High

Required Carter, Lionel; Miller, Emily; Thrash, Karl; Palmer, Kelly

Attendees:

Hi! Emily has a conflict now because of an important meeting with the Commissioner. Please let me know if you can meet earlier today.

Thanks, Brianna

-- 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

Tap to join from a mobile device (attendees only)

210-795-0506, (b) (6) US Toll 877-465-7975, (b) (6) US Toll Free

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free Global call-in numbers | Toll-free calling restrictions

From: Broderick, Brianna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C2403F4ADAE453CA6EFD28044DDEF37-BRODERICKB]

Sent: 8/24/2020 10:33:36 AM

To: Broderick, Brianna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2403f4adae453ca6efd28044ddef37-BRODERICKB]; Palmer, Kelly

[Kelly.Palmer@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Taylor, Craig

[Craig.Taylor@fda.hhs.gov]

Subject: Cybersecurity Briefing with Emily Miller

Location: Webex

Start: 8/25/2020 9:30:00 AM **End**: 8/25/2020 10:00:00 AM

Show Time As: Busy

Required Palmer, Kelly; Miller, Emily; Taylor, Craig

Attendees:

-- 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

Tap to join from a mobile device (attendees only)

210-795-0506,,(b) (6) US Toll 877-465-7975,(b) (6) US Toll Free

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

From: Wagner, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8A481C74326041D0B268D42F2D70D9F5-JOHN.WAGNER)

Sent: 8/24/2020 9:47:08 AM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Saunders, Shelisha

[Shelisha.Saunders@fda.hhs.gov]; Streeter, Candice [Candice.Streeter@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Cristinzio, Dayle

[Dayle.Cristinzio@fda.hhs.gov]; Mulieri, Chris [Charles.Mulieri@fda.hhs.gov]; Felberbaum, Michael

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

Subject: OEA FY21 Budget Review

Location: Webex

Start: 8/25/2020 3:00:00 PM **End**: 8/25/2020 4:00:00 PM

Show Time As: Busy

Required Saunders, Shelisha; Streeter, Candice; Walsh, Sandy; Miller, Emily; Cristinzio, Dayle; Mulieri, Chris; Felberbaum,

Attendees: Michael

-- 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

Tap to join from a mobile device (attendees only)

210-795-0506,,(b) (6) US Toll Free

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]

Sent: 8/24/2020 8:32:45 AM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Marks, Peter

[Peter.Marks@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Felberbaum, Michael

[Michael.Felberbaum@fda.hhs.gov]

CC: Tierney, Julia [Julia.Tierney@fda.hhs.gov]

Subject: Telecon: Comms Approach Location: 1-877-465-7975,,, (b) (6)

Start: 8/24/2020 9:15:00 AM **End**: 8/24/2020 9:45:00 AM

Show Time As: Busy

Importance: High

Required Lenihan, Keagan; Marks, Peter; Miller, Emily; Caccomo, Stephanie; Wagner, John; Felberbaum, Michael

Attendees:

Please confirm availability for this call.

Thanks.

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]

Sent: 8/23/2020 9:14:32 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: "Standing" CoS Meeting

Attachments: Untitled Attachment; Untitled Attachment; "Standing" CoS Meeting

Location: 1-877-465-7975,,(b) (6)

Start: 4/27/2020 2:30:00 PM **End**: 4/27/2020 3:00:00 PM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Monday from 2:30 PM to 3:00 PM

Required Abram, Anna; McBride, Maren; Roth, Lauren; Beardsley, Sara; Lutter, Randall; Anderson, Erika; Rebello, Heidi;

Attendees: Franklin, Joseph: Amin, Stacy: Flowers, Susan: Rom, Colin: Tobias, Lindsay: Helms Williams, Emily: Flahiye, James

ttendees: Franklin, Joseph; Amin, Stacy; Flowers, Susan; Rom, Colin; Tobias, Lindsay; Helms Williams, Emily; Flahive, James; Tantillo, Andrew; Klimczak, Katherine; Meister, Karen G; Alexander, Nicholas; Beshara, Nicholas; Guram, Jeet;

Schiller, Lowell; Lynch, Sarah; Koplow, Bret; Zeta, Lowell; George, Michelle; Gortler, David; Oxenham, Ann;

Felberbaum, Michael

Participant List Updated - 08/25/2020

HOST: (b) (6)

PIN: (b) (6)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/23/2020 9:53:53 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

> (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

CC: Emily Miller (b) (6)

Subject: quick touch point re media things

8/23/2020 10:00:00 AM Start: 8/23/2020 10:30:00 AM End:

Show Time As: Busy

Required Caccomo, Stephanie; Wagner, John; Felberbaum, Michael; Miller, Emily

Attendees:

Join by phone 210-795-0506 US Toll 877-465-7975 US Toll Free

Access code: (b) (6)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/23/2020 8:17:45 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

 $\label{lem:constraint} $$(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily $$(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily $$(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily $$(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Miller, Emily $$(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Miller, Peter [Pet$

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; McSeveney, Megan [Megan.McSeveney@fda.hhs.gov]; Hahn, Stephen [SH1@fda.hhs.gov]; Shah,

Anand [Anand.Shah@fda.hhs.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]

CC: Emily Miller (b) (6)

Subject: Embargoed media briefing SH/PM ** call-in details added

Start: 8/23/2020 3:00:00 PM **End**: 8/23/2020 3:30:00 PM

Show Time Busy

As:

Required Marks, Peter; Wagner, John; Miller, Emily; McNeill, Lorrie; Tierney, Julia; Frantz-Bohn, Susan; **Attendees**: Felberbaum, Michael; McSeveney, Megan; Hahn, Stephen; Shah, Anand; Lenihan, Keagan

When it's time, join the Webex meeting here.

Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Join meeting

Tap to join from a mobile device (attendees only)

210-795-0506,,(b) (6) US Toll US Toll US Toll Free

Join by phone 210-795-0506 US Toll 877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/23/2020 8:12:27 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Pratt, Michael (OS) [Michael.Pratt@hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Murphy, Ryan (OS) [Ryan.Murphy1@hhs.gov]; Caputo, Michael R (OS) [Michael.Caputo@hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Hahn,

Stephen [SH1@fda.hhs.gov]

CC: Emily Miller (b) (6); Pines, Wayne * [Wayne.Pines@fda.hhs.gov]

Subject: CP rollout prep for SH

Start: 8/23/2020 2:00:00 PM **End**: 8/23/2020 2:30:00 PM

Show Time As: Busy

Required Caccomo, Stephanie; Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily; Pratt, Michael (OS); Marks, Peter;

Attendees: Murphy, Ryan (OS); Caputo, Michael R (OS); Felberbaum, Michael; Hahn, Stephen

Join by phone 210-795-0506 US Toll 877-465-7975 US Toll Free

Access code: (b) (6)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C)

Sent: 8/23/2020 8:10:33 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Pratt, Michael (OS) [Michael.Pratt@hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]; Murphy, Ryan (OS) [Ryan.Murphy1@hhs.gov]; Caputo, Michael R (OS) [Michael.Caputo@hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Guevara,

Bessy [Bessy.Guevara@fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Emily Miller

Subject: Media Prep for Peter Marks

Start: 8/23/2020 11:00:00 AM End: 8/23/2020 11:30:00 AM

Show Time As: Busy

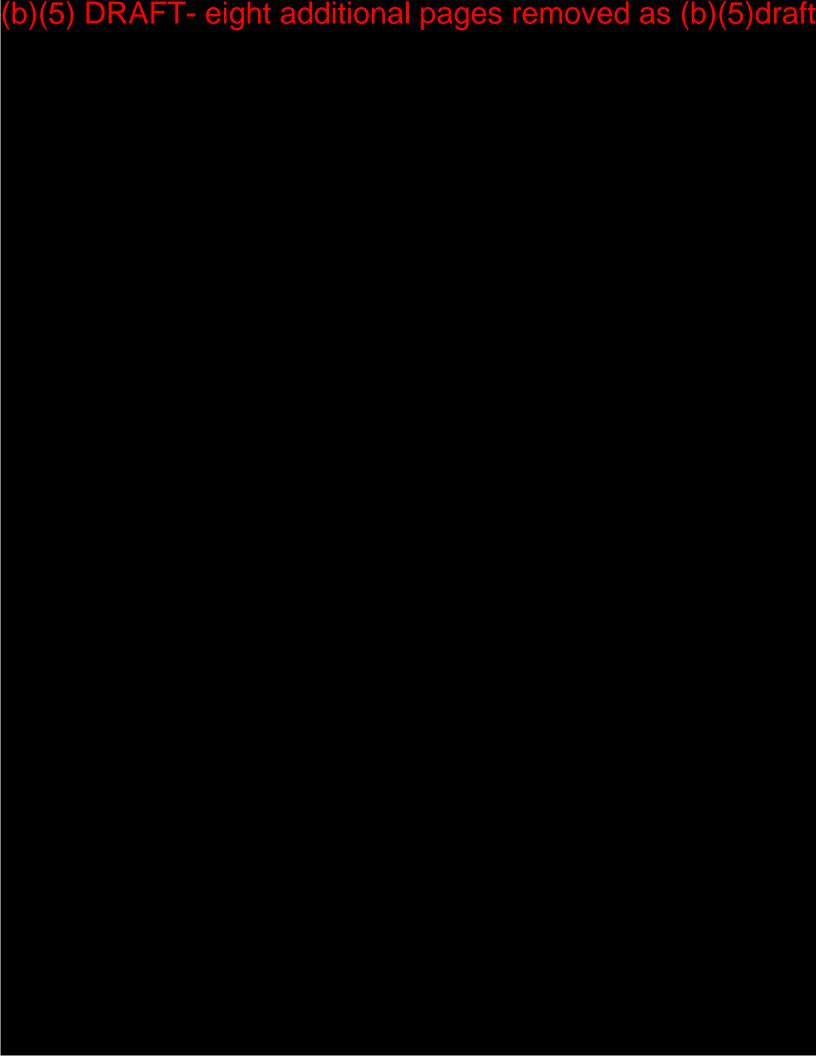
Required Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily; Pratt, Michael (OS); Marks, Peter; McNeill, Lorrie; Attendees:

Frantz-Bohn, Susan; Murphy, Ryan (OS); Caputo, Michael R (OS); Felberbaum, Michael; Guevara, Bessy; Tierney,

Julia; Emily Miller

Join by phone 210-795-0506 US Toll 877-465-7975 US Toll Free

Access code: (b) (6)



From: Guevara, Bessy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=58097BA8EDEA47AFB3338E671A43DC04-BESSY.GUEVA)

Sent: 8/22/2020 11:25:42 AM

To: Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Frantz-Bohn, Susan

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a10a749d49f9473aa2cd046423ee61bd-Kushal.Kada]; Guram, Jeet

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Finnen, April

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Adams, Michelle

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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=37e4582befea4a07b4ea5197163e7acb-Esteban.Ali]; Edmonds, Amanda
              [/o=ExchangeLabs/ou=Exchange Administrative Group
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1039b2acad94a4283d99df9f007f02a-Iris.Valent]; Leggin, Brooke
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; Miller, Emily
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Meister, Karen G
              [/o=ExchangeLabs/ou=Exchange Administrative Group]
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Bartell, Diane
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=83015d2cd30a4c62a4e661ac9324f4ee-BurkS]; Courtney, Brooke
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Mair, Michael
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Raza, Mark
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Beers, Donald
              [/o=ExchangeLabs/ou=Exchange Administrative Group]
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
CC:
                                                    ; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative
              Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Murphy, Ryan
              (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Traverse, Brad (OS)
              [/o=ExchangeLabs/ou=Exchange Administrative Group
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Lenihan, Keagan
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Subject:
              Rollout Check-In Meeting: Convalescent Plasma
Attachments:
              CP EUA PRESS RELEASE 8.23.20_ 715AM.docx; Messaging and comms plan for CP rollout_082320.docx;
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FINAL_QA_Convalescent Plasma_082220.docx

Location: WebEx

Start: 8/23/2020 9:30:00 AM 8/23/2020 10:30:00 AM End:

Show Time As: Busy

Required Tantillo, Andrew; Marks, Peter (Peter.Marks@fda.hhs.gov); Tierney, Julia; Frantz-Bohn, Susan

Attendees: (Susan.Frantzbohn@fda.hhs.gov); Rom, Colin; Everett, Christopher; Shah, Anand; Felberbaum, Michael; Kadakia,

Kushal; Guram, Jeet; Caccomo, Stephanie; Wagner, John; Mulieri, Chris; Walsh, Sandy; Cristinzio, Dayle; McSeveney, Megan; McNeill, Lorrie; Rath, Prakash (FDA); Finnen, April; Adams, Michelle; Hattis, Daniel; Nguyen, Michael A.; Aguilar, Paul; McBride, Maren; Jan Elicker; Fritsch, Beth F.; Shuman, Nikija; Alicea-Rivera, Esteban; Edmonds,

Amanda; Madni, Rubina; Zavagno, Denise; Wasserman, Jill; Pines, Wayne *; Maze, Tamara; Valentin-Bon, Iris; Leggin,

Brooke; Miller, Emily; Meister, Karen G; Bartell, Diane; Burk, Suzann; Courtney, Brooke; Mair, Michael

(Michael.Mair@fda.hhs.gov); Sadove, Elizabeth (Elizabeth.Sadove@fda.hhs.gov); Kimberly, Brad; Raza, Mark; Amin,

Stacy; Beers, Donald

8/23/2020 Update to include NEW timeline, QA and comm plan

This is a meeting regarding the convalescent plasma rollout, targeted for <u>Sunday</u>, <u>August 23</u>. (timing/tactics may change.)

Attached is the latest press release (pending final technical review), QA and the comm plan.

Rollout Meeting Agenda

- Intro (ROC Bessy Guevara)
- Timeline/Comms Plan Walkthrough (All)
- Questions/Discussion (All)

Bessy Guevara

Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration

Cell: (b) (6)
Bessy.Guevara@fda.hhs.gov





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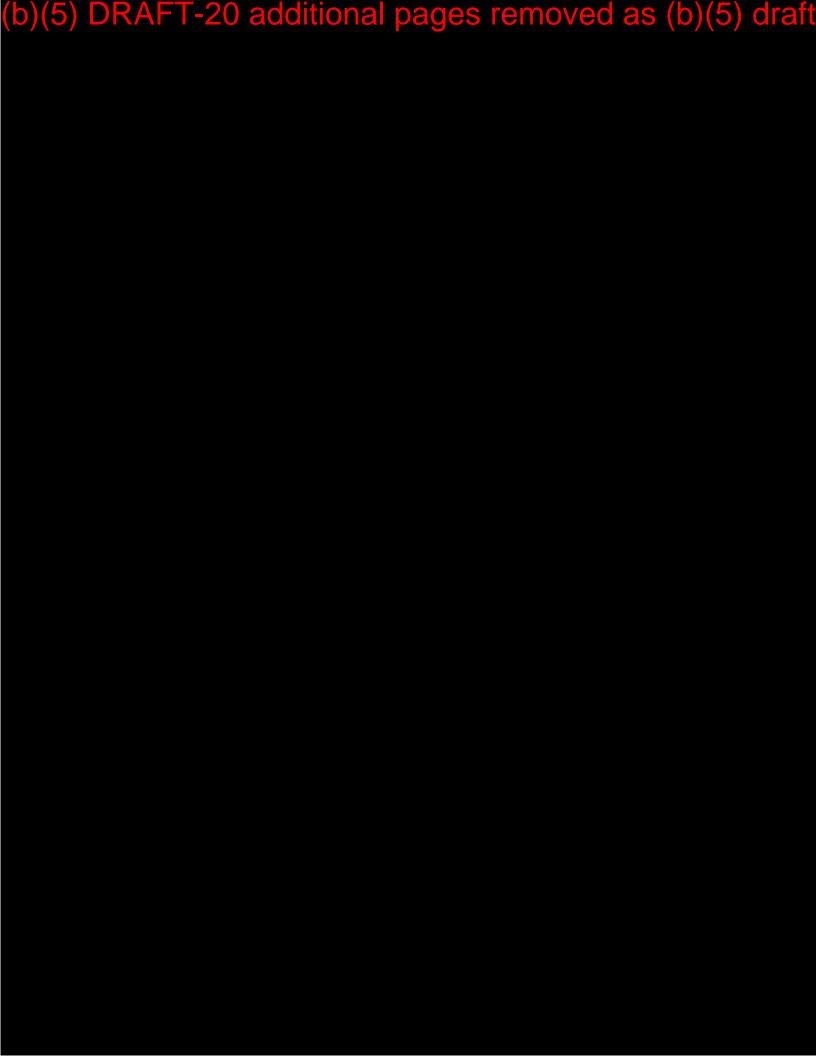
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Sent: 8/21/2020 3:52:05 PM

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Subject: Commissioner Briefing - Essential Medicines Executive Order - Materials

Attachments: Backgrounder Commissioner Briefing Essential Medicines EO Memo.docx; Commissioner Briefing_Essential Meds

EO.pptx

Location: Call in: Dial 1-866-507-5707 Passcode: (b) (6)

Start: 8/24/2020 12:30:00 PM End: 8/24/2020 1:30:00 PM

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Required Attendees: 'SH1@fda.hhs.gov'; Abernethy, Amy; Shah, Anand; Zeta, Lowell; Lenihan, Keagan; Helms Williams, Emily; Rebello, Heidi; Tobias, Lindsay; Flahive, James; Franklin, Joseph; Rom, Colin; Lutter, Randall; Hinton, Denise; Abram, Anna; Anderson, Erika; Tantillo, Andrew; McBride, Maren; Schiller, Lowell; Roth, Lauren; Amin, Stacy; Wagner, John; Throckmorton, Douglas C; Sipes, Grail; Clarke, Mary Beth; Corrigan-Curay, Jacqueline; Bennett, Carol; Gottlieb, Daniel; Hennessey, Lyndsay; Cunningham, Courtney C.; Buhse, Lucinda; Lehrfeld, Kimberly; Cavazzoni, Patrizia; Jensen, Valerie E; Thanh Hai, Mary; Stein, Peter; Kopcha, Michael; Roberts, Rosemary; Leissa, Brad G; Toigo, Theresa A; Witten, Celia (CBER); Richardson, Anita F (CBER); Loloei Marsal, Ana; Moran, Kristy; Jenkins, Yolanda; Jungman, Elizabeth; Abdoo, Mark; Maloney, Diane; Shuren, Jeff; Schwartz, Suzanne; Ricci, Linda J; Tomar, Eli; Mettler, Erik; Cave, Carol; McMeekin, Judith; Patel, Chaitali; Miller, Emily

Update (8/24/20) – Included EO link in Backgrounder

Update (8/23/20) – Materials (2)

- Backgrounder
- Tab A Presentation slides on Essential Medicines Executive Order

A briefing for the Commissioner has been scheduled to discuss Essential Medicines Executive Order on Monday, August 24, from 12:30 PM – 1:30 PM by conference call.

Date: Monday, August 24, 2020 **Time:** 12:30 PM – 1:30 PM **Location:** Conference Call

Note: Reminder to please be sure to mute your phone unless you are speaking.

Call-in Information:

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Please do not forward this invitation. If additional staff need to attend, please let me know.

Materials will be provided prior to the briefing.

OC/Office of the Executive Secretariat Contacts: Kristy Moran, (<u>Kristy.moran@fda.hhs.gov</u>) and Yolanda Jenkins, (<u>Yolanda.jenkins@fda.hhs.gov</u>)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

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[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schiller, Lowell

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Tantillo, Andrew

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Roth, Lauren

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Wagner, John

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; McBride, Maren

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Yiannas, Frank

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Boon, Caitlin

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=11917eb34d5445c3802eef2a3999e2e3-Caitlin.Boo]; Jenkins, Yolanda

[/o=ExchangeLabs/ou=Exchange Administrative Group

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[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Kavanaugh, Claudine

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e2bb33674f346b89bbee0b4ccc7b692-CKavanau]; Stearn, Douglas

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1662d8003b3e4ed29367bb7b7aaf54ff-STEARND]; Carroll, Laura

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9cb6e346de33480889c94630f0a6ea55-Laura.Carro]; Kux, Leslie

[/o=ExchangeLabs/ou=Exchange Administrative Group

 $(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c5fbcdbce154860ab23e1750d503dba-LKux]; \ McKinnon, \ Robin \ McKinnon, \ McK$

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=bd27415bf7ea4a9da98b7b6e6da43ad3-Robin.McKin]; Dooren, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=45519cc0bb9f41138b2e95fdfa06e432-Jennifer.Do]; Choiniere, Conradiant Control of the Control of Control of

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=053706355e7e41179c63737c416451fb-CChoinie]; Balentine, Douglas

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=6b28f8a3dd3e4c13ad33a74686846bcd-Douglas.Bal]; Carey, Emily Rose [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21a4cf80bae6477ea95932ffe37b4fc3-EmilyRose.C]; Taylor, Paige

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2f46091afaf2483abb72d8db96066f15-PTaylor]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Rebello, Heidi

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]

CC: 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]

Subject: Canceled: Cancelled, to be Rescheduled - Commissioner Briefing: Nutrition Innovation Strategy

Attachments: BriefingMemoNutrition_Aug2020.Clean.docx; Tab A - Nutrition Innovation Strategy Briefing.docx; Tab B - Nutrition

Innovation Strategy.docx; NISCommissionerHahnBriefing_Aug2020_CLEAN.pptx

Location: Dial in: 1-866-507-5707; Passcode: (b) (6)

Start: 8/24/2020 9:15:00 AM End: 8/24/2020 10:15:00 AM

Show Time As: Free Importance: High

Required Commissioner FDA; Hahn, Stephen (SH1@fda.hhs.gov); Abernethy, Amy; Franklin, Joseph; Shah, Anand; Lenihan,

Attendees: Keagan; Tobias, Lindsay; Zeta, Lowell; Amin, Stacy; Beckerman, Peter; Kropa, Halley; Abram, Anna; Anderson, Erika;

Rom, Colin; Schiller, Lowell; Tantillo, Andrew; Roth, Lauren; Wagner, John; McBride, Maren; Yiannas, Frank; Boon, Caitlin; Jenkins, Yolanda; Mayne, Susan; Kavanaugh, Claudine; Stearn, Douglas; Carroll, Laura; Kux, Leslie; McKinnon, Robin; Dooren, Jennifer; Choiniere, Conrad; Balentine, Douglas; Carey, Emily Rose; Taylor, Paige; Miller, Emily;

Rebello, Heidi

(8/24) Update - Briefing is cancelled but will be rescheduled for a later date.

See briefing materials attached.

A briefing for the Commissioner to discuss Nutrition Innovation Strategy has been scheduled for Monday, August 24, from 9:15 AM – 10:15 AM.

Date: Monday, August 24, 2020 **Time:** 9:15 AM – 10:15 AM

Note: Reminder to please be sure to mute your phone unless you are speaking.

Call-in Information:

Dial in: 1-866-507-5707 Passcode: (b) (6)

Please do not forward this invitation. If additional staff need to attend, please let me know.

OC/Office of the Executive Secretariat Contact: Yolanda K. Jenkins, 240-447-1524

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]

Sent: 8/21/2020 2:12:15 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]

Subject: Discussion on "comms going forward"

Location: 1-877-465-7975,,,(b) (6)

Start: 8/24/2020 2:00:00 PM **End**: 8/24/2020 2:30:00 PM

Show Time As: Busy

Required Miller, Emily; Wagner, John; Shah, Anand

Attendees:

Rescheduled at KL's request - 08/23/2020

From: Guevara, Bessy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=58097BA8EDEA47AFB3338E671A43DC04-BESSY.GUEVA)

Sent: 8/21/2020 1:46:41 PM

To: Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Marks, Peter

[Peter.Marks@fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; Everett, Christopher [Christopher.Everett@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Kadakia, Kushal [Kushal.Kadakia@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Mulieri, Chris [Charles.Mulieri@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Cristinzio, Dayle [Dayle.Cristinzio@fda.hhs.gov]; McSeveney, Megan [Megan.McSeveney@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Rath, Prakash (FDA)

[Prakash.Rath@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Adams, Michelle [Michelle.Adams@fda.hhs.gov]; Hattis, Daniel [Daniel.Hattis@fda.hhs.gov]; Nguyen, Michael A. [Michael.Nguyen1@fda.hhs.gov]; Aguilar, Paul [Paul.Aguilar@fda.hhs.gov]; McBride, Maren [Maren.McBride@fda.hhs.gov]; Elicker, Janet [janet.elicker@fda.hhs.gov]; Fritsch, Beth F.

[Beth.Fritsch@fda.hhs.gov]; Shuman, Nikija [Nikija.Shuman@fda.hhs.gov]; Alicea-Rivera, Esteban [Esteban.Alicea-

Rivera@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Madni, Rubina [Rubina.Madni@fda.hhs.gov]; Wasserman, Jill [Jill.Wasserman@fda.hhs.gov]; Pines, Wayne *

[Wayne.Pines@fda.hhs.gov]; Maze, Tamara [Tamara.Maze@fda.hhs.gov]; Valentin-Bon, Iris [Iris.Valentin-Bon@fda.hhs.gov]; Leggin, Brooke [Brooke.Leggin@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Meister, Karen G [Karen.Meister@fda.hhs.gov]; Zavagno, Denise [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18ed60daba0346b5b8f6277ecdb5bcb4-DZavagno]

CC: Bartell, Diane [Diane.Bartell@fda.hhs.gov]; Burk, Suzann [Suzann.Burk@fda.hhs.gov]; Courtney, Brooke

[Brooke.Courtney@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]; Kimberly, Brad [Brad.Kimberly@fda.hhs.gov]; Tantillo, Andrew

[Andrew.Tantillo@fda.hhs.gov]

Subject: Rollout Check-In Meeting: Convalescent Plasma

Location: WebEX

Start: 8/22/2020 9:30:00 AM **End**: 8/22/2020 10:30:00 AM

Show Time As: Busy

Required Guevara, Bessy; Marks, Peter (Peter.Marks@fda.hhs.gov); Tierney, Julia; Frantz-Bohn, Susan

Attendees: (Susan.Frantzbohn@fda.hhs.gov); Rom, Colin; Everett, Christopher; Shah, Anand; Felberbaum, Michael; Kadakia,

Kushal; Guram, Jeet; Caccomo, Stephanie; Wagner, John; Mulieri, Chris; Walsh, Sandy; Cristinzio, Dayle; McSeveney, Megan; McNeill, Lorrie; Rath, Prakash (FDA); Finnen, April; Adams, Michelle; Hattis, Daniel; Nguyen, Michael A.; Aguilar, Paul; McBride, Maren; Jan Elicker; Fritsch, Beth F.; Shuman, Nikija; Alicea-Rivera, Esteban; Edmonds,

Amanda; Madni, Rubina; Zavagno, Denise; Wasserman, Jill; Pines, Wayne *; Maze, Tamara; Valentin-Bon, Iris; Leggin,

Brooke; Miller, Emily; Meister, Karen G

Greetings,

This is a meeting regarding the convalescent plasma rollout. I appreciate your flexibility in joining on a Saturday.

Please forward to others to attend in your absence or others who are participating in the rollout.

This is being targeted for Sunday, August 23, but timing/tactics may change.

I hope to make the draft press release and communications plan available shortly before the call.

Rollout Meeting Agenda

- Intro/Roll call (ROC Bessy Guevara)
- Timeline/Comms Plan Walkthrough (All)
- Questions/Discussion (All)
- Next Steps (Bessy Guevara)

Kindly,

Bessy Guevara

Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration

Bessy.Guevara@fda.hhs.gov











-- 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

Tap to join from a mobile device (attendees only)

+1-210-795-0506, US Toll US Toll Free +1-877-465-7975,,

Join by phone

- +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, click here to view host information.

From: Guevara, Bessy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=58097BA8EDEA47AFB3338E671A43DC04-BESSY.GUEVA)

Sent: 8/21/2020 12:38:59 PM

To: Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; McSeveney, Megan [Megan.McSeveney@fda.hhs.gov]; Wasserman, Jill

[Jill.Wasserman@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]

Subject: CP rollout strategy discussion

Location: WebEX

Start: 8/21/2020 12:45:00 PM End: 8/21/2020 1:15:00 PM

Show Time As: Tentative

Required Miller, Emily; Caccomo, Stephanie; McSeveney, Megan; Wasserman, Jill; Wagner, John

Attendees:

Team,

Looks like the call dropped. Setting this time aside to discuss our strategy and timeline for the CP rollout.

Bessy Guevara

Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration

Cell: (b) (6)

Bessy.Guevara@fda.hhs.gov











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Meeting number (access code): (b) (6)

Meeting password: (b) (6)

Join meeting

Tap to join from a mobile device (attendees only)

+1-210-795-0506,, (b) (6) US Toll +1-877-465-7975,, (b) (6) US Toll Free

Join by phone

+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, click here to view host information.

Need help? Go to http://help.webex.com

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH)

Sent: 8/21/2020 9:57:04 AM

To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Marks, Peter

[Peter.Marks@fda.hhs.gov]; Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille];

Wagner, John [John.Wolf.Wagner@fda.hhs.gov]

CC: Guevara, Bessy [Bessy.Guevara@fda.hhs.gov]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; McSeveney,

Megan [Megan.McSeveney@fda.hhs.gov]; Wasserman, Jill [Jill.Wasserman@fda.hhs.gov]

Subject: Int Call - CP Rollout Timeline and Details (Touch Base)

Location: 8774657975,,,(b) (6)

Start: 8/21/2020 12:15:00 PM **End**: 8/21/2020 12:30:00 PM

Show Time As: Busy

Required Shah, Anand; Marks, Peter; Tierney, Julia; Miller, Emily; Wagner, John

Attendees:

-- 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

Tap to join from a mobile device (attendees only)

210-795-0506, **(b) (6)** US Toll 877-465-7975, **(b) (6)** US Toll Free

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free Global call-in numbers | Toll-free calling restrictions

If you are a host, click here to view host information.

From: Miller, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/20/2020 5:15:21 PM

To: Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Hatch act webex

Start: 7/24/2020 9:00:00 AM **End**: 7/24/2020 9:30:00 AM

Show Time As: Busy

When it's time, join your Webex meeting here.

Meeting number (access code): (b) (6)

Meeting password: (b) (6)



Honorary Co-Chairs

Hon. Bill Cassidy, M.D. Senator, Louisiana

Hon. Sheldon Whitehouse Senator, Rhode Island

Hon. Michael C. Burgess, M.D. Representative, Texas 26th District

Hon. Diana DeGette Representative, Colorado 1st District

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Reed V. Tuckson, M.D. Tuckson Health Connections Chair

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David Lansky, Ph.D.
Pacific Business Group on Health
Treasurer

Tanîsha Carino, Ph.D. Alexion

Adaeze Enekwechi, Ph.D., MPP IMPAQ

Dianne Faup, J.D. Speire Healthcare Strategies

Elizabeth Hall Anthem, Inc.

Peter M. Leibold, J.D. Ascension

Dan Mendelson, MPP Avalere Health

Margaret A. Murray
Association for Community Affiliated Plans

Francine Parker UAW Retiree Medical Benefits Trust

John C. Rother, J.D. National Coalition on Health Care

Kirsten Sloan
American Cancer Society Cancer
Action Network

Ronald Williams RW2 Enterprises, LLC

Sarah J. Dash, MPH Alliance for Health Policy President and CEO

Hon, John D. Rockefeller IV Founder and Chairman Emeritus June 12, 2020

Dr. Anand Shah U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

VIA ELECTRONIC MAIL

Dear Dr. Shah,

On behalf of the nonpartisan Alliance for Health Policy, I am writing to invite you to participate in an on-the-record conversation with reporters to discuss what you are currently working on as Deputy Commissioner for Medical and Scientific Affairs at the Food and Drug Administration.

We are more than willing to accommodate your schedule when planning this event and can coordinate with your team on an ideal date and time. The subject matter of the briefing is entirely up to your discretion. Still, we were envisioning you could discuss the FDA's work on COVID-19 vaccine clinical trials, testing development, and the U.S. drug supply chain.

This event is part of our Brazda Breakfast series that we conduct with APCO Worldwide. These briefings typically last between 45-60 minutes and attract about 20 reporters representing major media organizations, trade press, and Washington bureau reporters from regional publications. You would have time to make opening remarks, and then I would moderate a question and answer session. We would host the event on our Zoom platform, or other technology that is amenable to you.

Previous briefings have featured former FDA Commissioner Scott Gottlieb, CMS Administrator Seema Verma, former CMMI Director Adam Boehler, and former Director of the U.S. Domestic Policy Council Joe Grogan. We look forward to the opportunity to host you at an Alliance event in the near future.

Please reach out to me (SarahDash@allhealthpolicy.org) or my colleague Madeline Cree (MCree@allhealthpolicy.org) if you need anything from the Alliance team.

Sincerely,

Sarah Dash President & CEO



Thank you for your interest in inviting Anand Shah, MD, FDA Deputy Commissioner for Medical and Scientific Affairs to participate in your event. In an effort to better assist us in processing this request, please complete the form below and return to us. We will respond to you as quickly as possible regarding availability.

Please use as much space as needed in the form.

EVENT DETAILS		
Name of event	The Brazda Breakfast: Reporting on the Future of Health Care Perspectives on Health Policy from the Deputy Commissioner for Medical and Scientific Affairs at the Food and Drug Administration	
Preferred Date & Time	Thursday, August 20, 2020, 9:00-10:00 a.m. ET	
	Backup option Thursday, August 27, 2020, 9:00-10:00 a.m. ET	
Location	Zoom webinar platform or GoToWebinar platform	
Purpose/Theme	This event is part of our Brazda Breakfast series that we organize for health care and health policy-focused reporters to learn and hear from a variety of experts and leaders.	
Other FDA employees invited to speak	none	
Moderator of the event and/or individual introducing the Deputy Commissioner	Sarah J. Dash, President and CEO of the Alliance for Health Policy	
Host/Organizer. Please list both if the host is different than the sponsor	Host: Alliance for Health Policy Sponsor: APCO Worldwide	
Event registration fee and/or fee range for attendees	\$0	
	9:00 a.m Opening (5 minutes) Bill Pierce, Senior Director at APCO Worldwide, will make some brief opening remarks. Sarah J. Dash will introduce Dr. Shah and invite him to give opening remarks.	
Attach/Provide draft agenda (if available)	9:05 a.m Remarks from Dr. Shah or Moderated Discussion (10-15 minutes)	
	9:20 a.m. Question and Answer Session (25-40 minutes) Moderated by Sarah J. Dash of the Alliance for Health Policy	
	9:45 a.m. or 10:00 a.m. Closing	

[PAGE * MERGEFORMAT]

FORMAT DETAILS (please select)	
Keynote (include duration)	
Keynote plus QA (include duration for each)	Dr. Shah could have 10 minutes to make opening remarks, and then Sarah would moderate a question and answer session with reporter attendees for 30-45 minutes.
Fireside chat (include duration)	We can also format where there are 10-15 minutes of moderated discussion with Sarah using pre-approved questions and then go into a 25-40 minute QA session with reporter attendees.
Panelist (list invited and/or confirmed panelists)	
Luncheon or Dinner	

AUDIENCE	
Approximate number of attendees	10-15
Profile	reporters representing major media organizations, trade press, and Washington bureau reporters from regional publications
Members of Congress expected	0

MEDIA	
Open or closed to media	open
If open to press, provide a POC	Kathryn Martucci, Director of Policy and Programs, Alliance for Health Policy [HYPERLINK "mailto:kmartucci@allhealthpolicy.org"] (b) (6)
Webcast	yes
Video recorded	TBD

CONTENT DETAILS

Requested topic/Areas of discussion

The subject matter of the briefing is entirely up to Dr. Shah's discretion. Still, we were envisioning he could discuss his current priorities and successes as well as the FDA's work on COVID-19 vaccine clinical trials, testing development, and the U.S. drug supply chain.

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]

Sent: 8/19/2020 1:00:12 PM

To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Kadakia, Kushal [Kushal.Kadakia@fda.hhs.gov]; Pines, Wayne * [Wayne.Pines@fda.hhs.gov]; Traverse, Brad (OS) [Brad.Traverse@hhs.gov]; Alexander, Paul (OS) [Paul.Alexander@hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Shah / Brazda Breakfast (Alliance for Health Policy)

Attachments: Shah-invite-ahp-061220.pdf; Shah External Event Request Form_AllianceReporterBrieifing.doc

Location: Webinar / HHS Studio

Start: 8/20/2020 9:00:00 AM **End**: 8/20/2020 10:00:00 AM

Show Time As: Tentative

Required Wagner, John; Kadakia, Kushal; Pines, Wayne *; Traverse, Brad (OS); Alexander, Paul (OS); Miller, Emily

Attendees:

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/19/2020 10:59:27 AM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afacOcfa3c4b98913833e38a036e9f-Stephen.Hah]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Pre-Recorded Radio Interview: Conversations with Catherine, Hawaii Public Radio

Location: 808-942-4770

Start: 8/19/2020 3:00:00 PM **End**: 8/19/2020 3:10:00 PM

Show Time As: Tentative

Required Stephanie Caccomo; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov); Wagner, John; Miller, Emily

Attendees:

Back-up: 808-792-8248

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/19/2020 10:57:16 AM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Pre-Taped Interview: Jonathan Saupe, Hawaii News Now (HNN)

Location: Zoom: https://us02web.zoom.us/j/b) (6)

Start: 8/19/2020 3:15:00 PM **End**: 8/19/2020 3:25:00 PM

Show Time As: Tentative

Required Stephanie Caccomo; Michael Felberbaum (Michael.Felberbaum@fda.hhs.gov); Wagner, John; Miller, Emily

Attendees:

Topic: FDA Zoom meeting with HNN's Jonathan Saupe

Time: Aug 19, 2020 09:15 AM Hawaii

Join Zoom Meeting

https://us02web.zoom.us/

Meeting ID: (b) (6)
Passcode: (b) (6)

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]

Sent: 8/19/2020 10:22:29 AM

To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Pines, Wayne *

[/o=ExchangeLabs/ou=Exchange Administrative Group

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[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: Weekly Check-In: Upcoming Communications Forecast

Attachments: Canceled: Telecon: Weekly Check-In: Upcoming Communications Forecast; Telecon: Weekly Check-In: Upcoming

Communications Forecast; Canceled: Telecon: Weekly Check-In: Upcoming Communications Forecast

Location: Commissioner's Office (WO1/2217) or 1-877-465-7975,,, (b) (6)

Start: 4/23/2020 10:15:00 AM **End**: 4/23/2020 10:45:00 AM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Thursday from 10:15 AM to 10:45 AM

Required Hahn, Stephen (SH1@fda.hhs.gov); Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Shah, Anand; Rebello, Heidi

Attendees: (Heidi.Rebello@fda.hhs.gov); Rom, Colin; Caccomo, Stephanie; Felberbaum, Michael

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]

Sent: 8/19/2020 8:15:34 AM

To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: TELECON ONLY: Commissioner's Daily Check-In

Attachments: Untitled Attachment; Untitled Attachme

Untitled Attachment

Location: 1-877-465-7975,,(b) (6)

Start: 1/2/2019 9:00:00 AM End: 1/2/2019 9:30:00 AM

Show Time As: Free

Importance: High

Recurrence: Daily

every weekday from 9:00 AM to 9:30 AM

Required Hahn, Stephen (SH1@fda.hhs.gov); Lenihan, Keagan; Kux, Leslie; Sigg, Jim; Tyler, James; McWilliams, Carly; Mayne, Attendees: Susan; Marks, Peter; Zeller, Mitchell; Woodcock, Janet; Shuren, Jeff; Solomon, Steven M; Dickinson, Elizabeth (FDA);

Clarke, Mary Beth; Hebert, Angelique A.; McBride, Maren; Roth, Lauren; Witten, Celia (CBER); Musser, Steven M; Robb, Melissa; Lutter, Randall; Anderson, Erika; Abdoo, Mark; Abram, Anna; Schiller, Lowell; Boon, Caitlin; Rebello, Heidi; Beardsley, Sara; Hinton, Denise; Cox, Lucinda; Tantillo, Andrew; Mital, Michele; Franklin, Joseph; Alexander, Nicholas; Flannery, Ellen; Forfa, Tracey; Amin, Stacy; Tomasello, Jennifer; Prater, Donald; Yiannas, Frank; Cavazzoni, Patrizia; Beshara, Nicholas; Helms Williams, Emily; Abernethy, Amy; Gross, Karas; Pazdur, Richard; Kluetz, Paul; Kim, Tamy; Rom, Colin; Klimczak, Katherine; Olivarria, Frank; Tobias, Lindsay; Flahive, James; Araojo, Richardae; Sheehy, Janice; McMeekin, Judith; Tierney, Julia; Shah, Anand; Patel, Chaitali; Solberg, Tim; Guram, Jeet; Koplow, Bret; Zeta,

Lowell; Meister, Karen G; Theoret, Marc; Mair, Michael; Finnen, April; Caccomo, Stephanie; Felberbaum, Michael; Dooren, Jennifer; Brubach, April; George, Michelle; Raza, Mark; Dayle Cristinzio (Dayle.Cristinzio@fda.hhs.gov); Vasisht, Kaveeta; Gortler, David; Wagner, John; Beaver, Julia; Oxenham, Ann

Please do not forward this meeting series. If you need to send a delegate in your place, please contact Frank Olivarria, Janice Sheehy, or Heidi Rebello. Thanks!

Note: New dial-in effective Monday, August 10, 2020.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/18/2020 9:32:35 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: In-Person Meeting: Emily Miller / Dr. Hahn

Location: HHS FDA Suite (HHH-749D)

Start: 8/19/2020 11:30:00 AM **End**: 8/19/2020 12:00:00 PM

Show Time As: Tentative

Required Keagan Lenihan; Miller, Emily

Attendees:

COVID-19 AEG Daily Meeting

1-877-465-7975, code: (b) (6)

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

Agenda Topic	Presenters
Commissioner's Critical Information Requirements (CCIR)	
Commissioner	Stephen Hahn
Chief of Staff	Keagan Lenihan
Principal Deputy Commissioner/CIO	Amy Abernethy
Deputy Commissioner for Medical and Scientific Affairs	Anand Shah
Product Centers (Supply Chain, Shortages, Therapeutics, Vaccines, Inspection Delays, User Fee Delays)	, Blood Supply, Clinical Trials,
	CBER
	CDER
	CDRH
	СТР
	OFPR
	CFSAN
	CVM
ORA	Judy McMeekin/Michael Rogers
OPLIA/OGPS	Erika Anderson / Mark Abdoo
осс	Stacy Amin / Mark Raza
Office of Operations	Jim Sigg / Angel Hebert
OFBA	Jay Tyler/ Bill Tootle
IMG Updates	Michael Mair/CAPT Mignone
Communication	
Communication currently in process for clearance	Heidi Rebello
Communication proposed for weekday/ weekend	Stephanie Caccomo April Finnen/ Jen Dooren
Discussions / Decisions / Actions / Follow-up	All

COVID-19 AEG Daily Meeting

1-877-465-7975, code: (b) (6)

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

Agenda Topic	Presenters
Commissioner's Critical Information Requirements (CCIR)	
Commissioner	Stephen Hahn
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Product Centers (Supply Chain, Shortages, Therapeutics, Vaccines, Inspection Delays, User Fee Delays)	, Blood Supply, Clinical Trials,
	CBER
	CDER
	CDRH
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	CFSAN
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ORA	Judy McMeekin/Michael Rogers
OPLIA/OGPS	Erika Anderson / Mark Abdoo
осс	Stacy Amin / Mark Raza
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Communication	
Communication currently in process for clearance	Heidi Rebello
Communication proposed for weekday/ weekend	Stephanie Caccomo April Finnen/ Jen Dooren
Discussions / Decisions / Actions / Follow-up	All

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Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Araojo, Richardae
[Richardae.Araojo@fda.hhs.gov]; Block, Molly [Molly.Block@fda.hhs.gov]; Berrellez, Jessica
[Jessica.Berrellez@fda.hhs.gov]; Mignone, Alfred [Alfred.Mignone@fda.hhs.gov]; Schiller, Lowell
[Lowell.Schiller@fda.hhs.gov]; Roth, Lauren [Lauren.Roth@fda.hhs.gov]; Raghuwanshi, Rakesh
[Rakesh.Raghuwanshi@fda.hhs.gov]; Cason, Winona [Winona.Cason@fda.hhs.gov]; Domanski, Jeffrey
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[Deirdre.Hussey@fda.hhs.gov]; Huttenlocker, Denise [Denise.Huttenlocker@fda.hhs.gov]; Schweitzer, Roxanne K
[Roxanne.Schweitzer@fda.hhs.gov]; Stone, Eric [Eric.Stone@fda.hhs.gov]; Barth, Janelle
[Janelle.Barth@fda.hhs.gov]; Pillai, Segaran [Segaran.Pillai@fda.hhs.gov]; Cho, David S (CBER)
[David.Cho@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Demers, Donald E
[Donald.Demers@fda.hhs.gov]; Boon, Caitlin [Caitlin.Boon@fda.hhs.gov]; Gutierrez, Sacha
[Sacha.Gutierrez@fda.hhs.gov]; Slikker, William [William.Slikker@fda.hhs.gov]; Franklin, Joseph
[Joseph.Franklin@fda.hhs.gov]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Yiannas, Frank
[Frank.Yiannas@fda.hhs.gov]; Zeller, Mitchell [Mitchell.Zeller@fda.hhs.gov]; Clarke, Mary Beth
[Marybeth.Clarke@fda.hhs.gov]; Rebello, Heidi [Heidi.Rebello@fda.hhs.gov]; Cavazzoni, Patrizia
[Patrizia.Cavazzoni@fda.hhs.gov]; Beach, Carter [Carter.Beach@fda.hhs.gov]; Tyler, James
[James.Tyler@fda.hhs.gov]; Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]; Keller, Melanie
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[Douglas.Throckmorton@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Musser, Steven M
[Steven.Musser@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Mair, Michael
[Michael.Mair@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Branch,
Tiffany [Tiffany.Branch@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Abdoo, Mark
[Mark.Abdoo@fda.hhs.gov]; McMeekin, Judith [Judith.McMeekin@fda.hhs.gov]; Rogers, Michael
[Michael.Rogers@fda.hhs.gov]; Forfa, Tracey [Tracey.Forfa@fda.hhs.gov]; Solomon, Steven M
[Steven.Solomon@fda.hhs.gov]; Shuren, Jeff [Jeff.Shuren@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov];
Marks, Peter [Peter.Marks@fda.hhs.gov]; Carter, Lionel [Lionel.Carter@fda.hhs.gov]; Tootle, William
[William.Tootle@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Hebert, Angelique A.
[Angelique.Hebert@fda.hhs.gov]; Sigg, Jim [Jim.Sigg@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Lenihan,
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Subject: Canceled: COVID-19 Agency Executive Group Meeting - No meeting on 9/10/2020

Attachments: Agenda_COVID19 AEG Meeting.pdf

Start: 9/10/2020 4:00:00 PM **End**: 9/10/2020 4:30:00 PM

Show Time As: Free

Importance: High

Recurrence: (none)

Due to scheduling conflicts, today's AEG will be canceled.

Thank you for your flexibility and support.

Best, Denise

COVID-19 AEG Daily Meeting

1-877-465-7975, code: (b) (6)

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

Agenda Topic	Presenters
Commissioner's Critical Information Requirements (CCIR)	
Commissioner	Stephen Hahn
Chief of Staff	Keagan Lenihan
Principal Deputy Commissioner/CIO	Amy Abernethy
Deputy Commissioner for Medical and Scientific Affairs	Anand Shah
Product Centers (Supply Chain, Shortages, Therapeutics, Vaccines, Inspection Delays, User Fee Delays)	, Blood Supply, Clinical Trials,
	CBER
	CDER
	CDRH
	СТР
	OFPR
	CFSAN
	CVM
ORA	Judy McMeekin/Michael Rogers
OPLIA/OGPS	Erika Anderson / Mark Abdoo
осс	Stacy Amin / Mark Raza
Office of Operations	Jim Sigg / Angel Hebert
OFBA	Jay Tyler/ Bill Tootle
IMG Updates	Michael Mair/CAPT Mignone
Communication	
Communication currently in process for clearance	Heidi Rebello
Communication proposed for weekday/ weekend	Stephanie Caccomo April Finnen/ Jen Dooren
Discussions / Decisions / Actions / Follow-up	All

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Subject: Canceled: COVID-19 Agency Executive Group Meeting - 8 OCT meeting is cancelled

Attachments: Agenda_COVID19 AEG Meeting.pdf

Start: 10/8/2020 4:00:00 PM **End**: 10/8/2020 4:30:00 PM

Show Time As: Free
Importance: High
Recurrence: (none)

Conference Line information:

Number: 877-465-7975 Attendee Code: (b) (6) Host Code: (b) (6)

Dear Colleagues,

At the Commissioners request, the AEG meetings will be held Tuesdays and Thursdays from 4:30 PM - 5:00 PM. AEG meetings have been established to share timely updates, establish policy/guidance, provide direction, and make decisions related to the ongoing COVID-19 pandemic emergency response activities.

Thank you for your flexibility and support.

Best, Denise

Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND] Sent: 8/18/2020 4:01:06 PM To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hahn, Stephen [SH1@fda.hhs.gov]; 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]; 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]; Rebello, Heidi [Heidi.Rebello@fda.hhs.gov]; Clarke, Mary Beth [Marybeth.Clarke@fda.hhs.gov]; Zeller, Mitchell [Mitchell.Zeller@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Franklin, Joseph [Joseph.Franklin@fda.hhs.gov]; Slikker, William [William.Slikker@fda.hhs.gov]; Gutierrez, Sacha [Sacha.Gutierrez@fda.hhs.gov]; Boon, Caitlin [Caitlin.Boon@fda.hhs.gov]; Demers, Donald E [Donald.Demers@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Pillai, Segaran [Segaran.Pillai@fda.hhs.gov]; Barth, Janelle [Janelle.Barth@fda.hhs.gov]; Stone, Eric [Eric.Stone@fda.hhs.gov]; Schweitzer, Roxanne K [Roxanne.Schweitzer@fda.hhs.gov]; Huttenlocker, Denise [Denise.Huttenlocker@fda.hhs.gov]; Hussey, Deirdre [Deirdre.Hussey@fda.hhs.gov]; Barfell, Glenda F [Glenda.Barfell@fda.hhs.gov]; Domanski, Jeffrey [Jeffrey.Domanski@fda.hhs.gov]; Cason, Winona [Winona.Cason@fda.hhs.gov]; Raghuwanshi, Rakesh [Rakesh.Raghuwanshi@fda.hhs.gov]; Roth, Lauren [Lauren.Roth@fda.hhs.gov]; Schiller, Lowell [Lowell.Schiller@fda.hhs.gov]; Mignone, Alfred [Alfred.Mignone@fda.hhs.gov]; Berrellez, Jessica [Jessica.Berrellez@fda.hhs.gov]; Block, Molly [Molly.Block@fda.hhs.gov]; Araojo, Richardae [Richardae.Araojo@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@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]; 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]; Ross, Bruce [Bruce.Ross@fda.hhs.gov]; Torres-Rivera, Sahra [Sahra.Torres-Rivera@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; McWilliams, Carly [Carly.McWilliams@fda.hhs.gov]; Arsenault, Sam [Samuel.Arsenault@fda.hhs.gov]; Bouvier, Robert [Robert.Bouvier@fda.hhs.gov]; Garner, Kimberly [Kimberly, Garner@fda.hhs.gov]; Washington, Jacqueline (OC) [Jacqueline.Washington@fda.hhs.gov]; Williams, Vanessa [Vanessa.Williams@fda.hhs.gov]; Zablan Jr., Russell [Russell.Zablan@fda.hhs.gov]; Chiverton, Evan [Evan.Chiverton@fda.hhs.gov]; Measer, Gregory [Gregory.Measer@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]; Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]; Aldridge, Megan [Megan.Aldridge@fda.hhs.gov]; McBride, Maren [Maren.McBride@fda.hhs.gov]; Johanson, Elaine [Elaine.Johanson@fda.hhs.gov]; Klimczak, Katherine [Katherine.Klimczak@fda.hhs.gov]; Nabakowski, Andrei [Andrei.Nabakowski@fda.hhs.gov]; Thompson, Lori [Lori.Thompson@fda.hhs.gov]; Brubach, April [April.Brubach@fda.hhs.gov]; Rubenstein, Alister [Alister.Rubenstein@fda.hhs.gov]; Hoffman, Allison [Allison.Hoffman@fda.hhs.gov]; Frasca, Dominic [Dominic.Frasca@fda.hhs.gov]; Andrews, Raymond [RJ.Andrews@fda.hhs.gov]; Walia, Nina [Nina.Walia@fda.hhs.gov]; Valo, Gina [Gina.Valo@fda.hhs.gov]; Stearn, Douglas [Douglas.Stearn@fda.hhs.gov]; Burrows, Vanessa [Vanessa.Burrows@fda.hhs.gov]; Cristinzio, Dayle [Dayle.Cristinzio@fda.hhs.gov]; Russo, Mark [Mark.Russo@fda.hhs.gov]; Echegoyen, Edwin [Edwin.Echegoyen@fda.hhs.gov]; Venerio, Nelson [Nelson.Venerio@fda.hhs.gov]; Francisco, Herminio [Herminio.Francisco@fda.hhs.gov]; Knapp, Melissa

; Dawson, Chantal [Chantal.Dawson@fda.hhs.gov];

[Melissa.Knapp@fda.hhs.gov]; Tautges, Mada [Mada.Tautges@fda.hhs.gov]; Miller, Holly

[Holly.Miller@fda.hhs.gov]; (b) (6)

Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; DeBeck, Heidi

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c142647655544b82a6a16eb575fcb729-Heidi.Debec]

Subject: COVID-19 Agency Executive Group Meeting

Attachments: Agenda COVID19 AEG Meeting.pdf; Canceled: COVID-19 Agency Executive Group Meeting - No meeting on

9/10/2020; Canceled: COVID-19 Agency Executive Group Meeting - 8 OCT meeting is cancelled

Location: 1-877-465-7975, code: 155 94 328#

Start: 6/16/2020 4:00:00 PM **End**: 6/16/2020 4:30:00 PM

Show Time As: Busy

Recurrence: Weekly

every Tuesday and Thursday from 4:00 PM to 4:30 PM

RequiredHahn, 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; 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; Rebello, Heidi; Clarke, Mary Beth; Zeller, Mitchell; Yiannas, Frank; Caccomo, Stephanie; Franklin, Joseph; Slikker, William; Gutierrez, Sacha; Boon, Caitlin; Demers, Donald E; Finnen, April; Cho, David S (CBER); Pillai, Segaran; Barth, Janelle; Stone, Eric; Schweitzer, Roxanne K; Huttenlocker, Denise; Hussey, Deirdre; Barfell, Glenda F; Domanski, Jeffrey; Cason, Winona; Raghuwanshi, Rakesh; Roth, Lauren; Schiller,

Lowell; Mignone, Alfred; Berrellez, Jessica; Block, Molly; Araojo, Richardae; Abram, Anna; Wagner, John

Conference Line information:

Number: 877-465-7975 Attendee Code: (b) (6) Host Code: (b) (6)

Dear Colleagues,

At the Commissioners request, the AEG meetings will be held Tuesdays and Thursdays from 4:30 PM – 5:00 PM. AEG meetings have been established to share timely updates, establish policy/guidance, provide direction, and make decisions related to the ongoing COVID-19 pandemic emergency response activities.

Thank you for your flexibility and support.

Best, Denise From: Palmer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1EFE882D2038426FAF0ECB4C8BBBE020-PALMERK]

Sent: 8/18/2020 11:30:50 AM

To: Palmer, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1efe882d2038426faf0ecb4c8bbbe020-PALMERK]; Broderick, Brianna

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2403f4adae453ca6efd28044ddef37-BRODERICKB]; Demers, Donald E

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee9abcfa1b9a4d2a9222bd5ebb733faf-DDEMERS]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: Tour of the White Oak Campus with Emily Miller

Location: Meet in Emily's Office in 32/5348

Start: 8/19/2020 2:30:00 PM **End**: 8/19/2020 3:30:00 PM

High

Show Time As: Free

Required Broderick, Brianna; Demers, Donald E; Miller, Emily

Attendees:

Importance:

From: Palmer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1EFE882D2038426FAF0ECB4C8BBBE020-PALMERK]

Sent: 8/18/2020 11:29:44 AM

To: Palmer, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1efe882d2038426faf0ecb4c8bbbe020-PALMERK]; Tse, Tania [Tania.Tse@fda.hhs.gov]; Hightower, Kisha (FDA) [Kisha.Hightower@fda.hhs.gov]; Broderick, Brianna [Brianna.Broderick@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Alston, Lillian (FDA)

[Lillian.Alston@fda.hhs.gov]

CC: Williams, Jacqueline (FDA) [Jacqueline.Williams@fda.hhs.gov]; Beale, Shawniece [Shawniece.Beale@fda.hhs.gov]

Subject: Human Resources Briefing with Emily Miller

Location: WebEx

Start: 8/24/2020 10:00:00 AM **End**: 8/24/2020 10:30:00 AM

Show Time As: Busy

Required Tse, Tania; Hightower, Kisha (FDA); Broderick, Brianna; Miller, Emily; Alston, Lillian (FDA)

Attendees:

Tania, I think you are on leave, but including you as fyi. Kisha, I hope this date/time works for you.

- Do not delete or change any of the following text. --

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Meeting password: (b) (6)

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210-795-0506, (b) (6) US Toll 877-465-7975, (b) (6) US Toll Free

Join by phone

210-795-0506 US Toll 877-465-7975 US Toll Free

Global call-in numbers | Toll-free calling restrictions

If you are a host, click here to view host information.

From: Broderick, Brianna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C2403F4ADAE453CA6EFD28044DDEF37-BRODERICKB)

Sent: 8/18/2020 11:27:56 AM

To: Broderick, Brianna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2403f4adae453ca6efd28044ddef37-BRODERICKB]; Palmer, Kelly

[Kelly.Palmer@fda.hhs.gov]; Akbari, Asim [Asim.Akbari@fda.hhs.gov]

Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Onboarding Ethics Briefing

Location: Webex Only

Start: 8/26/2020 1:30:00 PM **End**: 8/26/2020 2:00:00 PM

Show Time As: Busy

Required Broderick, Brianna; Palmer, Kelly; Akbari, Asim

Attendees:

CC:

----Original Appointment-----

From: Broderick, Brianna < Brianna. Broderick@fda.hhs.gov>

Sent: Friday, August 7, 2020 3:42 PM

To: Broderick, Brianna; Palmer, Kelly; Akbari, Asim

Subject: Onboarding Ethics Briefing

When: Wednesday, August 26, 2020 1:30 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex Only

Meeting with **Asim Akbari**, Director, Division of Ethics and Integrity and **Emily Miller**, Assistant Commissioner for Media Affairs.

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877-465-7975 US Toll Free Global call-in numbers | Toll-free calling restrictions

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Need help? Go to http://help.webex.com

From: Wasserman, Jill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A757986D59F4210A83E2DE2B6DD23A8-JILL.WASSER]

Sent: 8/27/2020 5:32:46 PM

To: Wasserman, Jill [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0a757986d59f4210a83e2de2b6dd23a8-Jill.Wasser]; Hunt, Alison [Alison.Hunt@fda.hhs.gov]; Caccomo, Stephanie [Stephanie.Caccomo@fda.hhs.gov]; Hatch, Shannon

[Shannon.Hatch@fda.hhs.gov]; Kimberly, Brad [Brad.Kimberly@fda.hhs.gov]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Tantibanchachai, Chanapa [Chanapa.Tantibanchachai@fda.hhs.gov]; Wagner, John [John.Wolf.Wagner@fda.hhs.gov]; Leboeuf,

Andrew [Andrew.Leboeuf@fda.hhs.gov]; Booze, Kristen [Kristen.Booze@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Birnkrant, Debra B [Debra.Birnkrant@fda.hhs.gov]; Murray, Jeffrey S [Jeffrey.Murray@fda.hhs.gov]; Kraus, Stefanie [Stefanie.Kraus@fda.hhs.gov]; Mulieri, Chris

[Charles.Mulieri@fda.hhs.gov]; Braithwaite, Sonia [Sonia.Braithwaite@fda.hhs.gov]; Setthachayanon, Nick [Nick.Setthachayanon@fda.hhs.gov]; Cristinzio, Dayle [Dayle.Cristinzio@fda.hhs.gov]; Fritsch, Beth F.

[Beth.Fritsch@fda.hhs.gov]; Walsh, Sandy [Sandy.Walsh@fda.hhs.gov]; Cavazzoni, Patrizia

[Patrizia.Cavazzoni@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Alexander, Nicholas [Nicholas.Alexander@fda.hhs.gov]; Adams, Michelle [Michelle.Adams@fda.hhs.gov]; Aguilar, Paul

[Paul.Aguilar@fda.hhs.gov]; Schipper, Jodi [jodi.schipper@fda.hhs.gov]; Hubbard, Jane [Jane.Hubbard@fda.hhs.gov]; Black, Jennifer [Jennifer.Black@fda.hhs.gov]; Thorpe, Valarie [Valarie.Thorpe@fda.hhs.gov]; Elicker, Janet [Janet.Elicker@fda.hhs.gov]; Nguyen, Michael A. [Michael.Nguyen1@fda.hhs.gov]; Earley, Rosemary [Rosemary.Earley@fda.hhs.gov]; Horne, Eric [Eric.Horne@fda.hhs.gov]; Guevara, Bessy [Bessy.Guevara@fda.hhs.gov]; Meister, Karen G

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER] Strachman-Miller, Jason [Jason.Strachman-Miller@fda.hhs.gov]; Felberbaum, Michael

[Michael.Felberbaum@fda.hhs.gov]; Sherwat, Adam [Adam.Sherwat@fda.hhs.gov]; Chan-Tack, Kirk [Kirk.Chan-

Tack@fda.hhs.gov]; Henriques, Maria [Maria.Henriques@fda.hhs.gov]; Cooper, Mildred

[Mildred.Cooper@fda.hhs.gov]; Campbell, Christopher [Christopher.Campbell@fda.hhs.gov]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]; Baumgartner, Kristofer [Kristofer.Baumgartner@fda.hhs.gov]; Staton, Anna [Anna.Staton@fda.hhs.gov]; Wyllie, James-Denton [James-Denton.Wyllie@fda.hhs.gov]; Jerrick, Morgan

[Morgan.Liscinsky@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Rawlings, Kimberly

[Kimberly.Rawlings@fda.hhs.gov]

Subject: Rollout-Comms Coordination: FDA Broadens EUA for remdesivir to include all hospitalized patients

Location: WebEx, see body invite

 Start:
 8/28/2020 10:30:00 AM

 End:
 8/28/2020 11:00:00 AM

Show Time As: Busy

CC:

Required Wasserman, Jill; Alison Hunt (Alison.Hunt@fda.hhs.gov); Caccomo, Stephanie; Hatch, Shannon; Kimberly, Brad;
Attendees: Miller, Emily; Tantibanchachai, Chanapa; Wagner, John; Leboeuf, Andrew; Booze, Kristen; Farley, John; Birnkrant,

Debra B; Murray, Jeffrey S; Kraus, Stefanie; Mulieri, Chris; Braithwaite, Sonia; Setthachayanon, Nick; Cristinzio, Dayle; Fritsch, Beth F.; Sandy Walsh (Sandy.Walsh@fda.hhs.gov); Cavazzoni, Patrizia; Anderson, Erika; Alexander, Nicholas; Meister, Karen G; Adams, Michelle; Aguilar, Paul; Schipper, Jodi; Hubbard, Jane; Black, Jennifer; Thorpe,

Valarie; Elicker, Janet; Nguyen, Michael A.; Earley, Rosemary; Horne, Eric; Bessy Guevara

(Bessy.Guevara@fda.hhs.gov)

UPDATE: Here is the link to the DRAFT comms plan to ensure we have a coordinated rollout. Feel free to go in and edit as appropriate. We will discuss at 10:30. Best -Jill

Dear, all,

This meeting is to have a discussion about FDA's communications strategy regarding the expansion of the EUA for remdesivir. I will share a DRAFT communications plan before the meeting.

Please forward to others to attend in your absence or others who would benefit from being part of the conversation.

Rollout Meeting Agenda

- Intro/Roll call (Wasserman, OEA)
- Comms Plan Discussion (All)
- Questions/Discussion (All)
- Next Steps (Wasserman, OEA)

Enjoy your evenings,

Jill Wasserman, MPH

Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration

Work Cell: (b) (6)
Jill.Wasserman@fda.hhs.gov





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Meeting password: (b) (6)

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/27/2020 5:42:32 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]; 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]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: Comms Daily Check-In

Attachments: Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: 1-877-465-7975, (b) (6)

Start: 8/28/2020 4:45:00 PM **End**: 8/28/2020 5:00:00 PM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Monday, Tuesday, Wednesday, Thursday, and Friday from 4:45 PM to 5:00 PM

Required Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Shah, Anand; Rom, Colin; Wagner, John; Miller, Emily

From: Saunders, Shelisha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEF2B83443674D87A7E9F87B51654683-SHELISHA.SA]

Sent: 8/28/2020 8:16:48 AM

To: Saunders, Shelisha [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=bef2b83443674d87a7e9f87b51654683-Shelisha.Sa]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: OMA Personnel & Staffing

Location: WebEx

Start: 8/31/2020 1:30:00 PM **End**: 8/31/2020 2:00:00 PM

Show Time As: Free

Importance: High

Required Miller, Emily

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/28/2020 6:48:32 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; OC OEA OMA-Press

[OCOEAOMA-Press@fda.hhs.gov]; Jarrell, Kristin [Kristin.Jarrell@fda.hhs.gov]; Herring, Kenneth (Lee)

[Kenneth.Herring@fda.hhs.gov]; Rebello, Heidi [Heidi.Rebello@fda.hhs.gov]

CC: Hatch, Shannon [Shannon.Hatch@fda.hhs.gov]; Kahn, Jeremy [Jeremy.Kahn@fda.hhs.gov]; Hunt, Alison

[Alison.Hunt@fda.hhs.gov]; Felberbaum, Michael [Michael.Felberbaum@fda.hhs.gov]

Subject: OMA Virtual "Happy Hour"

Location: Zoom at bottom!

Start: 9/2/2020 3:30:00 PM **End**: 9/2/2020 4:30:00 PM

Show Time As: Tentative

Required OC OEA OMA-Press; Jarrell, Kristin; Herring, Kenneth (Lee); Rebello, Heidi (Heidi.Rebello@fda.hhs.gov)

Attendees:

Let's gather for another OMA virtual "happy hour" to welcome the latest additions to the team as well as say goodbye to some of our dear colleagues! And to celebrate and appliand the amazing work of our team!!

I'll do another round of FDA trivia, so get your thinking caps ready!

When it's the end of summer and you give up on lookin good



Topic: OMA Happy Hour

Time: Sep 2, 2020 03:30 PM Eastern Time (US and Canada)

Join Zoom Meeting

(b) (6)

Meeting ID: (b) (6)

One tap mobile

+13017158592,(b) (6)

US (Germantown) 13126266799,,(b) (6)

+(Chicago)

Dial by your location

- +1 301 715 8592 US (Germantown)
- +1 312 626 6799 US (Chicago)
- +1 646 876 9923 US (New York)
- +1 408 638 0968 US (San Jose)
- +1 669 900 6833 US (San Jose)
- +1 253 215 8782 US (Tacoma)
- +1 346 248 7799 US (Houston)

Meeting ID: (b) (6)

Find your local number: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/27/2020 5:47:08 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]; 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]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: Comms Daily Weekend Check-In Attachments: Untitled Attachment; Untitled Attachment

Location: 1-877-465-7975,,(b) (6)

Start: 8/29/2020 10:00:00 AM **End**: 8/29/2020 10:15:00 AM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Sunday and Saturday from 10:00 AM to 10:15 AM

Required Lenihan, Keagan; Shah, Anand; Rom, Colin; Wagner, John; Miller, Emily

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/27/2020 4:55:51 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Canceled: Media Interview: Kiran Stacey, Financial Times

Location: Shannon Hatch will connect SH to the Reporter

Start: 8/29/2020 2:00:00 PM **End**: 8/29/2020 2:30:00 PM

Show Time As: Free

Importance: High

Required Wagner, John; Caccomo, Stephanie; Hatch, Shannon

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 1:46:25 PM

Subject: Lawyers meeting

Start: 8/28/2020 2:00:00 PM **End**: 8/28/2020 2:30:00 PM

Show Time As: Busy

Recurrence: (none)

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]

Sent: 8/27/2020 8:27:52 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Kimberly, Brad

[Brad.Kimberly@fda.hhs.gov]; Hatch, Shannon [Shannon.Hatch@fda.hhs.gov]

Subject: OMA management check-in

Start: 8/27/2020 11:00:00 AM **End**: 8/27/2020 11:30:00 AM

Show Time As: Tentative

Required Miller, Emily; Kimberly, Brad; Hatch, Shannon

Attendees:

Join by phone 210-795-0506 US Toll 877-465-7975 US Toll Free

Access code: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/26/2020 4:44:35 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: Touch Base with Commissioner, COS, & Dep Commissioner Shah

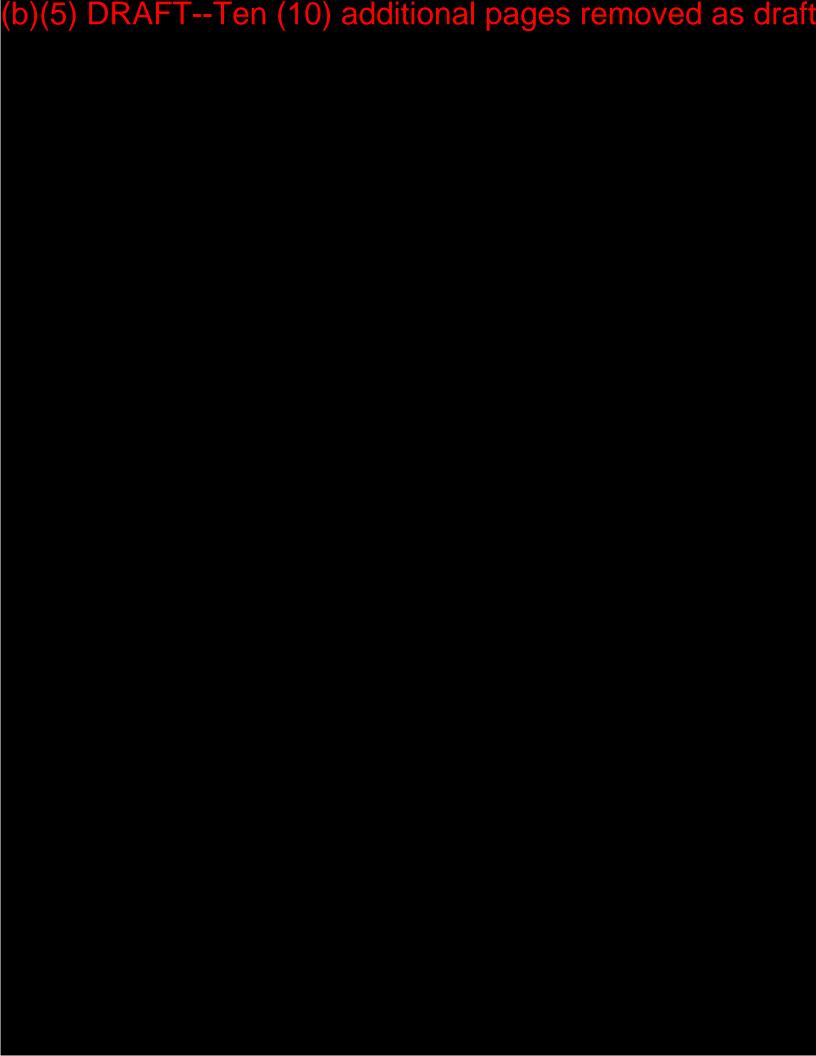
Location: 1-877-465-7975,,(b) (6)

Start: 8/26/2020 5:45:00 PM **End**: 8/26/2020 6:15:00 PM

Show Time As: Busy

Importance: High

Required Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily



From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL

Sent: 8/26/2020 9:26:05 AM

To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, Stephanie

[Stephanie.Caccomo@fda.hhs.gov]; Hatch, Shannon [Shannon.Hatch@fda.hhs.gov]

CC: Kimberly, Brad [Brad.Kimberly@fda.hhs.gov]; Raza, Mark [Mark.Raza@fda.hhs.gov]; Rebello, Heidi

[Heidi.Rebello@fda.hhs.gov]

Subject: Press Paper SOP/Media Inquiries ** SOP Attached **

Attachments: FDA CLEARANCE AND DISTRIBUTION PROCESS FOR PRESS PAPER-8.18.20.doc

Location: Webex

Start: 8/26/2020 1:00:00 PM **End**: 8/26/2020 1:30:00 PM

Show Time As: Busy

Required Felberbaum, Michael; Lenihan, Keagan; Amin, Stacy; Wagner, John; Miller, Emily; Caccomo, Stephanie; Hatch,

Attendees: Shannon

Meeting Purpose: Overview of established SOP (attached) that predictably and efficiently allows for FDA press paper to be reviewed and cleared by appropriate parties for technical and legal accuracy. We will also discuss media inquiry clearance.

1-210-795-0506 US Toll 877-465-7975 US Toll Free

Access code: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/25/2020 2:41:37 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Rom, Colin

[Colin.Rom@fda.hhs.gov]

Subject: In-Person (@ WO) Touch Base: Rom/Miller/Wagner/Shah/Lenihan/Hahn

Location: Commissioner's Suite (WO1/2217)

Start: 8/27/2020 12:00:00 PM **End**: 8/27/2020 12:30:00 PM

Show Time As: Busy

Required Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily; Rom, Colin

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 10:28:39 PM

Subject: Draft strat comms plan

Start: 8/26/2020 3:00:00 PM **End**: 8/26/2020 3:30:00 PM

Show Time As: Busy

Recurrence: (none)

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Wolf, Ailis * [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C489E12E8B3A4082974AC4E202212D74-AILIS.WOLF]

Sent: 8/25/2020 4:13:49 PM

To: Wolf, Ailis * [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c489e12e8b3a4082974ac4e202212d74-Ailis.Wolf]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

CC: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Saghafi, Michelle

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c64d4cc782a94188ae15e0549dffefca-Michelle.Sa]

Subject: Canceled: Head Shot Session - Emily Miller **Location**: FDA Courtroom Studio - Bldg 1, Room 1307

Start: 9/3/2020 11:00:00 AM **End**: 9/3/2020 11:30:00 AM

Show Time As: Free

Importance: High

Required Miller, Emily

Attendees:

Date: September 3, 2020 Time: 11-11:30 a.m.

Location: FDA Courtroom Studio - Bldg 1, Room 1307

Notes:

You are confirmed to have your official photo taken for FDA.. You will be sent 5-7 different photos to choose from after your session. Please indicate your photo selection (1-2) and the final photo will be retouched and emailed to you for your use. You have the option to have a version of your photo produced following the session with the American flag; please indicate your preference at your photo session.

Recommended wardrobe for photo session:

Women: dark blazer with blouse or light-colored solid shirt, or dress (preferably not a turtleneck). A print would work if it complements the blazer but nothing big, busy or shiny. For jewelry, keep it simple – avoid items that distract from your face, including overly sparkly jewelry.

From: FDA Commissioner [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E34B2C290A94C4A8D7AF884727CD0F8-COMMISSIONE]

Sent: 8/25/2020 11:34:36 AM

To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Hahn, Stephen

[SH1@fda.hhs.gov]; Abernethy, Amy [Amy.Abernethy@fda.hhs.gov]; Franklin, Joseph [Joseph.Franklin@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Tobias, Lindsay [Lindsay.Tobias@fda.hhs.gov]; Zeta, Lowell [Lowell.Zeta@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Beckerman, Peter [Peter.Beckerman@fda.hhs.gov]; Taylor, Paige [Paige.Taylor@fda.hhs.gov]; Schifter, Karen [Karen.Schifter@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Schiller, Lowell [Lowell.Schiller@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Roth, Lauren [Lauren.Roth@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; McBride, Maren [Maren.McBride@fda.hhs.gov]; Kavanaugh, Claudine [Claudine.Kavanaugh@fda.hhs.gov]; Stearn, Douglas [Douglas.Stearn@fda.hhs.gov]; Carroll, Laura [Laura.Carroll@fda.hhs.gov]; Kux, Leslie [Leslie.Kux@fda.hhs.gov]; McKinnon, Robin [Robin.McKinnon@fda.hhs.gov]; Dooren, Jennifer [Jennifer.Dooren@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Rom, Colin [Colin.Rom@fda.hhs.gov]; Yiannas, Frank [Frank.Yiannas@fda.hhs.gov]; Boon, Caitlin [Caitlin.Boon@fda.hhs.gov]; Mayne, Susan [Susan.Mayne@fda.hhs.gov]; Choiniere, Conrad

[Conrad.Choiniere@fda.hhs.gov]; Balentine, Douglas [Douglas.Balentine@fda.hhs.gov]; Carey, Emily Rose [EmilyRose.Carey@fda.hhs.gov]; Rebello, Heidi [Heidi.Rebello@fda.hhs.gov]; Jenkins, Yolanda

[Yolanda.Jenkins@fda.hhs.gov]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Varnado, Martina [Martina.Varnado@fda.hhs.gov]; O'Neill, Jeff [Jeff.ONeill@fda.hhs.gov]

Subject: New Time of Rescheduled: Commissioner Briefing: Nutrition Innovation Strategy

Attachments: BriefingMemoNutrition_Aug2020.Updated.docx; Tab A - Nutrition Innovation Strategy Briefing.docx; Tab B -

Nutrition Innovation Strategy.docx; NISCommissionerHahnBriefing_Aug2020_CLEAN.pptx

Location: Dial in: 1-866-507-5707 Passcode: (b) (6)

Start: 8/25/2020 3:00:00 PM **End**: 8/25/2020 4:00:00 PM

Show Time As: Busy

Required FDA Commissioner; Hahn, Stephen (SH1@fda.hhs.gov); Abernethy, Amy; Franklin, Joseph; Shah, Anand; Lenihan, Attendees: Keagan (Keagan.Lenihan@fda.hhs.gov); Tobias, Lindsay; Zeta, Lowell; Amin, Stacy; Beckerman, Peter; Taylor, Paige;

Schifter, Karen; Anderson, Erika; Schiller, Lowell; Tantillo, Andrew; Roth, Lauren; Wagner, John; Miller, Emily; McBride, Maren; Kavanaugh, Claudine; Stearn, Douglas; Carroll, Laura; Kux, Leslie; McKinnon, Robin; Dooren, Jennifer; Abram, Anna; Rom, Colin; Yiannas, Frank; Boon, Caitlin; Mayne, Susan; Choiniere, Conrad; Balentine,

Douglas; Carey, Emily Rose; Rebello, Heidi; Jenkins, Yolanda

(8/25) Update – See New timing for this Commissioner Briefing which is still scheduled for today, August 25 but now from 3:00 pm – 4:00 pm.

8/25 - Unfortunately, the Commissioner is no longer able to join this briefing at 10 am - but we are working to reschedule for either later in the day or very soon after.

(8/24) Update - Briefing is cancelled but will be rescheduled for a later date.

See briefing materials attached.

A briefing for the Commissioner to discuss Nutrition Innovation Strategy has been re-scheduled for Tuesday, August 25, from 3:00 PM – 4:00 PM.

Date: Tuesday, August 25, 2020 **New Time: 3:00 PM – 4:00 PM**

Note: Reminder to please be sure to mute your phone unless you are speaking.

Call-in Information:

Dial in: 1-866-507-5707 Passcode: (b) (6)

Please do not forward this invitation. If additional staff need to attend, please let me know.

OC/Office of the Executive Secretariat Contact: Yolanda K. Jenkins, 240-447-1524

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/25/2020 11:24:36 AM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan

[Keagan.Lenihan@fda.hhs.gov]; Shah, Anand [Anand.Shah@fda.hhs.gov]; Wagner, John

[John.Wolf.Wagner@fda.hhs.gov]; Miller, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]

Subject: In-Person Meeting (@ WO): Comms Strategy

Location: Commissioner's Suite (WO1/2217)

Start: 8/28/2020 11:00:00 AM **End**: 8/28/2020 11:30:00 AM

Show Time As: Busy

Required Lenihan, Keagan; Shah, Anand; Wagner, John; Miller, Emily

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/24/2020 10:34:16 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; Caccomo, 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]

Subject: Live Interview: Gayle King, CBS Morning News
Location: SH CO Residence (Mobile Crew Arrives 4 AM MDT)

Start: 8/25/2020 8:00:00 AM **End**: 8/25/2020 8:05:00 AM

Show Time As: Busy

Required Wagner, John; Miller, Emily; Caccomo, Stephanie; Felberbaum, Michael

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Sent: 8/24/2020 5:50:25 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; 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]

Subject: Canceled: Media Hold

Location: TBD - POC: EMiller/SCaccomo

Start: 8/27/2020 7:00:00 AM **End**: 8/27/2020 8:30:00 AM

Show Time As: Free

Importance: High

Required Wagner, John; Miller, Emily; Felberbaum, Michael; Stephanie Caccomo

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH)

Sent: 8/24/2020 5:49:57 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Miller, Emily

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=349ea636fe504b488adf664e48ce87e6-Emily.Mille]; 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]

Subject: Radio Interview: Sam Malone, Houston, TX

Location: SH to call (b) (6)

Start: 8/28/2020 8:00:00 AM **End**: 8/28/2020 8:10:00 AM

Show Time As: Tentative

Required Wagner, John; Miller, Emily; Felberbaum, Michael; Stephanie Caccomo

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Mother's Day **Location**: United States

Start: 5/9/2020 8:00:00 PM **End**: 5/10/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/21/2020 8:00:00 PM **End**: 4/22/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Tax Day Location: United States

Start: 4/14/2020 8:00:00 PM **End**: 4/15/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Election Day Location: United States

Start: 11/6/2023 7:00:00 PM **End**: 11/7/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Thanksgiving Day Location: United States

Start: 11/23/2016 7:00:00 PM **End**: 11/24/2016 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Easter Day Location: United States

Start: 4/11/2020 8:00:00 PM **End**: 4/12/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Columbus Day Location: United States

Start: 10/8/2023 8:00:00 PM **End**: 10/9/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Election Day Location: United States

Start: 11/7/2016 7:00:00 PM **End**: 11/8/2016 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Presidents' Day Location: United States

Start: 2/16/2020 7:00:00 PM **End**: 2/17/2020 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Labor Day Location: United States

Start: 9/3/2023 8:00:00 PM **End**: 9/4/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Columbus Day **Location**: United States

Start: 10/9/2016 8:00:00 PM **End**: 10/10/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/19/2020 7:00:00 PM **End**: 1/20/2020 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Father's Day **Location**: United States

Start: 6/17/2023 8:00:00 PM **End**: 6/18/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Labor Day Location: United States

Start: 9/4/2016 8:00:00 PM **End**: 9/5/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/28/2019 7:00:00 PM End: 11/29/2019 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Memorial Day Location: United States

Start: 5/28/2023 8:00:00 PM **End**: 5/29/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Father's Day **Location**: United States

Start: 6/18/2016 8:00:00 PM **End**: 6/19/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Thanksgiving Day Location: United States

Start: 11/27/2019 7:00:00 PM **End**: 11/28/2019 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Mother's Day **Location**: United States

Start: 5/13/2023 8:00:00 PM **End**: 5/14/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Memorial Day Location: United States

Start: 5/29/2016 8:00:00 PM **End**: 5/30/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:23 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/26/2026 7:00:00 PM **End**: 11/27/2026 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Election Day **Location**: United States

Start: 11/4/2019 7:00:00 PM **End**: 11/5/2019 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/25/2023 8:00:00 PM **End**: 4/26/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Mother's Day **Location**: United States

Start: 5/7/2016 8:00:00 PM **End**: 5/8/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:23 PM

Subject: Thanksgiving Day Location: United States

Start: 11/25/2026 7:00:00 PM **End**: 11/26/2026 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Columbus Day **Location**: United States

Start: 10/13/2019 8:00:00 PM **End**: 10/14/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Tax Day Location: United States

Start: 4/16/2023 8:00:00 PM **End**: 4/17/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/26/2016 8:00:00 PM **End**: 4/27/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:23 PM

Subject: Election Day Location: United States

Start: 11/2/2026 7:00:00 PM **End**: 11/3/2026 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Labor Day Location: United States

Start: 9/1/2019 8:00:00 PM **End**: 9/2/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Easter Day Location: United States

Start: 4/8/2023 8:00:00 PM End: 4/9/2023 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Tax Day Location: United States

Start: 4/17/2016 8:00:00 PM **End**: 4/18/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:23 PM

Subject: Columbus Day Location: United States

Start: 10/11/2026 8:00:00 PM **End**: 10/12/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Father's Day **Location**: United States

Start: 6/15/2019 8:00:00 PM **End**: 6/16/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Presidents' Day Location: United States

Start: 2/19/2023 7:00:00 PM **End**: 2/20/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Easter Day Location: United States

Start: 3/26/2016 8:00:00 PM **End**: 3/27/2016 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:23 PM

Subject: Labor Day Location: United States

Start: 9/6/2026 8:00:00 PM **End**: 9/7/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Memorial Day **Location**: United States

Start: 5/26/2019 8:00:00 PM **End**: 5/27/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/15/2023 7:00:00 PM **End**: 1/16/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Presidents' Day **Location**: United States

Start: 2/14/2016 7:00:00 PM **End**: 2/15/2016 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:22 PM

Subject: Independence Day (Observed)

Location: United States

Start: 7/2/2026 8:00:00 PM **End**: 7/3/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Mother's Day Location: United States

Start: 5/11/2019 8:00:00 PM **End**: 5/12/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: New Year's Day (Observed)

Location: United States

Start: 1/1/2023 7:00:00 PM **End**: 1/2/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/17/2016 7:00:00 PM End: 1/18/2016 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:22 PM

Subject: Father's Day **Location**: United States

Start: 6/20/2026 8:00:00 PM **End**: 6/21/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/23/2019 8:00:00 PM **End**: 4/24/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Christmas Holiday (Observed)

Location: United States

Start: 12/25/2022 7:00:00 PM **End**: 12/26/2022 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/26/2015 7:00:00 PM **End**: 11/27/2015 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:22 PM

Subject: Memorial Day **Location**: United States

Start: 5/24/2026 8:00:00 PM **End**: 5/25/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Easter Day Location: United States

Start: 4/20/2019 8:00:00 PM **End**: 4/21/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/24/2022 7:00:00 PM **End**: 11/25/2022 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Thanksgiving Day Location: United States

Start: 11/25/2015 7:00:00 PM **End**: 11/26/2015 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:22 PM

Subject: Mother's Day Location: United States

Start: 5/9/2026 8:00:00 PM **End**: 5/10/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Tax Day Location: United States

Start: 4/14/2019 8:00:00 PM **End**: 4/15/2019 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Thanksgiving Day Location: United States

Start: 11/23/2022 7:00:00 PM **End**: 11/24/2022 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Election Day Location: United States

Start: 11/2/2015 7:00:00 PM **End**: 11/3/2015 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:22 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/21/2026 8:00:00 PM **End**: 4/22/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Presidents' Day Location: United States

Start: 2/17/2019 7:00:00 PM **End**: 2/18/2019 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Election Day Location: United States

Start: 11/7/2022 7:00:00 PM **End**: 11/8/2022 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Columbus Day **Location**: United States

Start: 10/11/2015 8:00:00 PM **End**: 10/12/2015 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Tax Day Location: United States

Start: 4/14/2026 8:00:00 PM **End**: 4/15/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/20/2019 7:00:00 PM End: 1/21/2019 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Columbus Day Location: United States

Start: 10/9/2022 8:00:00 PM **End**: 10/10/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Labor Day Location: United States

Start: 9/6/2015 8:00:00 PM **End**: 9/7/2015 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Easter Day Location: United States

Start: 4/4/2026 8:00:00 PM **End**: 4/5/2026 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/22/2018 7:00:00 PM **End**: 11/23/2018 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Labor Day Location: United States

Start: 9/4/2022 8:00:00 PM **End**: 9/5/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: New Year's Eve Location: United States

Start: 12/30/2012 7:00:00 PM **End**: 12/31/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Presidents' Day **Location**: United States

Start: 2/15/2026 7:00:00 PM **End**: 2/16/2026 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Thanksgiving Day Location: United States

Start: 11/21/2018 7:00:00 PM **End**: 11/22/2018 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Father's Day **Location**: United States

Start: 6/18/2022 8:00:00 PM **End**: 6/19/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Christmas Day Location: United States

Start: 12/24/2012 7:00:00 PM **End**: 12/25/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/18/2026 7:00:00 PM **End**: 1/19/2026 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Veteran's Day (Observed)

Location: United States

Start: 11/11/2018 7:00:00 PM **End**: 11/12/2018 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Memorial Day Location: United States

Start: 5/29/2022 8:00:00 PM **End**: 5/30/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Christmas Eve **Location**: United States

 Start:
 12/23/2012 7:00:00 PM

 End:
 12/24/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/27/2025 7:00:00 PM **End**: 11/28/2025 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Election Day Location: United States

Start: 11/5/2018 7:00:00 PM **End**: 11/6/2018 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Mother's Day Location: United States

Start: 5/7/2022 8:00:00 PM **End**: 5/8/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Veteran's Day Location: United States

Start: 11/10/2012 7:00:00 PM **End**: 11/11/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Thanksgiving Day Location: United States

Start: 11/26/2025 7:00:00 PM **End**: 11/27/2025 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Columbus Day **Location**: United States

Start: 10/7/2018 8:00:00 PM **End**: 10/8/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/26/2022 8:00:00 PM **End**: 4/27/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Halloween Location: United States

Start: 10/30/2012 8:00:00 PM **End**: 10/31/2012 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Election Day Location: United States

Start: 11/3/2025 7:00:00 PM **End**: 11/4/2025 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Labor Day Location: United States

Start: 9/2/2018 8:00:00 PM **End**: 9/3/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Tax Day Location: United States

Start: 4/17/2022 8:00:00 PM **End**: 4/18/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Independence Day Location: United States

Start: 7/3/2012 8:00:00 PM **End**: 7/4/2012 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Columbus Day Location: United States

Start: 10/12/2025 8:00:00 PM **End**: 10/13/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Father's Day Location: United States

Start: 6/16/2018 8:00:00 PM **End**: 6/17/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Easter Day Location: United States

Start: 4/16/2022 8:00:00 PM **End**: 4/17/2022 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Juneteenth Location: United States

Start: 6/18/2012 8:00:00 PM **End**: 6/19/2012 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Labor Day Location: United States

Start: 8/31/2025 8:00:00 PM **End**: 9/1/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Memorial Day **Location**: United States

Start: 5/27/2018 8:00:00 PM **End**: 5/28/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Presidents' Day Location: United States

Start: 2/20/2022 7:00:00 PM **End**: 2/21/2022 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:14 PM

Subject: Peace Officers Memorial Day

Location: United States

Start: 5/14/2012 8:00:00 PM **End**: 5/15/2012 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Father's Day **Location**: United States

Start: 6/14/2025 8:00:00 PM **End**: 6/15/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Mother's Day **Location**: United States

Start: 5/12/2018 8:00:00 PM **End**: 5/13/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/16/2022 7:00:00 PM End: 1/17/2022 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:14 PM

Subject: St. Patrick's Day Location: United States

Start: 3/16/2012 8:00:00 PM **End**: 3/17/2012 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Memorial Day **Location**: United States

Start: 5/25/2025 8:00:00 PM **End**: 5/26/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/24/2018 8:00:00 PM **End**: 4/25/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: New Year's Day (Observed)

Location: United States

Start: 12/30/2021 7:00:00 PM End: 12/31/2021 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:14 PM

Subject: Valentine's Day Location: United States

Start: 2/13/2012 7:00:00 PM **End**: 2/14/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Mother's Day **Location**: United States

Start: 5/10/2025 8:00:00 PM **End**: 5/11/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Tax Day Location: United States

Start: 4/16/2018 8:00:00 PM **End**: 4/17/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Christmas Holiday (Observed)

Location: United States

Start: 12/23/2021 7:00:00 PM **End**: 12/24/2021 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:14 PM

Subject: Groundhog Day **Location**: United States

Start: 2/1/2012 7:00:00 PM **End**: 2/2/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/22/2025 8:00:00 PM **End**: 4/23/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Easter Day Location: United States

Start: 3/31/2018 8:00:00 PM End: 4/1/2018 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/25/2021 7:00:00 PM **End**: 11/26/2021 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:14 PM

Subject: New Year's Day Location: United States

Start: 12/31/2011 7:00:00 PM End: 1/1/2012 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Easter Day Location: United States

Start: 4/19/2025 8:00:00 PM **End**: 4/20/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Presidents' Day Location: United States

Start: 2/18/2018 7:00:00 PM **End**: 2/19/2018 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Thanksgiving Day Location: United States

Start: 11/24/2021 7:00:00 PM **End**: 11/25/2021 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Tax Day Location: United States

Start: 4/14/2025 8:00:00 PM **End**: 4/15/2025 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/14/2018 7:00:00 PM **End**: 1/15/2018 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Election Day Location: United States

Start: 11/1/2021 8:00:00 PM **End**: 11/2/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Presidents' Day Location: United States

Start: 2/16/2025 7:00:00 PM **End**: 2/17/2025 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/23/2017 7:00:00 PM **End**: 11/24/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Columbus Day **Location**: United States

Start: 10/10/2021 8:00:00 PM **End**: 10/11/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/19/2025 7:00:00 PM **End**: 1/20/2025 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Thanksgiving Day Location: United States

Start: 11/22/2017 7:00:00 PM **End**: 11/23/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Labor Day Location: United States

Start: 9/5/2021 8:00:00 PM **End**: 9/6/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/28/2024 7:00:00 PM **End**: 11/29/2024 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Veteran's Day (Observed)

Location: United States

Start: 11/9/2017 7:00:00 PM **End**: 11/10/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Independence Day (Observed)

Location: United States

Start: 7/4/2021 8:00:00 PM **End**: 7/5/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Thanksgiving Day Location: United States

Start: 11/27/2024 7:00:00 PM **End**: 11/28/2024 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Election Day Location: United States

Start: 11/6/2017 7:00:00 PM **End**: 11/7/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Father's Day **Location**: United States

Start: 6/19/2021 8:00:00 PM **End**: 6/20/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Election Day **Location**: United States

Start: 11/4/2024 7:00:00 PM **End**: 11/5/2024 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Columbus Day Location: United States

Start: 10/8/2017 8:00:00 PM **End**: 10/9/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Memorial Day Location: United States

Start: 5/30/2021 8:00:00 PM **End**: 5/31/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:20 PM

Subject: Columbus Day **Location**: United States

Start: 10/13/2024 8:00:00 PM **End**: 10/14/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Labor Day Location: United States

Start: 9/3/2017 8:00:00 PM **End**: 9/4/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Mother's Day Location: United States

Start: 5/8/2021 8:00:00 PM **End**: 5/9/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Labor Day Location: United States

Start: 9/1/2024 8:00:00 PM **End**: 9/2/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Father's Day **Location**: United States

Start: 6/17/2017 8:00:00 PM **End**: 6/18/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/20/2021 8:00:00 PM **End**: 4/21/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Father's Day Location: United States

Start: 6/15/2024 8:00:00 PM **End**: 6/16/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Memorial Day Location: United States

Start: 5/28/2017 8:00:00 PM **End**: 5/29/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Tax Day Location: United States

Start: 4/14/2021 8:00:00 PM **End**: 4/15/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Memorial Day **Location**: United States

Start: 5/26/2024 8:00:00 PM **End**: 5/27/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Mother's Day **Location**: United States

Start: 5/13/2017 8:00:00 PM **End**: 5/14/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Easter Day Location: United States

Start: 4/3/2021 8:00:00 PM End: 4/4/2021 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Mother's Day **Location**: United States

Start: 5/11/2024 8:00:00 PM **End**: 5/12/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/25/2017 8:00:00 PM **End**: 4/26/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Presidents' Day **Location**: United States

Start: 2/14/2021 7:00:00 PM **End**: 2/15/2021 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Administrative Professionals Day

Location: United States

Start: 4/23/2024 8:00:00 PM **End**: 4/24/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Tax Day Location: United States

Start: 4/17/2017 8:00:00 PM **End**: 4/18/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/17/2021 7:00:00 PM End: 1/18/2021 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Tax Day Location: United States

Start: 4/14/2024 8:00:00 PM **End**: 4/15/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Easter Day Location: United States

Start: 4/15/2017 8:00:00 PM **End**: 4/16/2017 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:18 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/26/2020 7:00:00 PM **End**: 11/27/2020 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Easter Day Location: United States

Start: 3/30/2024 8:00:00 PM **End**: 3/31/2024 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Presidents' Day **Location**: United States

Start: 2/19/2017 7:00:00 PM **End**: 2/20/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Thanksgiving Day Location: United States

Start: 11/25/2020 7:00:00 PM **End**: 11/26/2020 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Presidents' Day **Location**: United States

Start: 2/18/2024 7:00:00 PM **End**: 2/19/2024 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/15/2017 7:00:00 PM End: 1/16/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Election Day Location: United States

Start: 11/2/2020 7:00:00 PM **End**: 11/3/2020 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Martin Luther King Day

Location: United States

Start: 1/14/2024 7:00:00 PM **End**: 1/15/2024 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:16 PM

Subject: New Year's Day (Observed)

Location: United States

Start: 1/1/2017 7:00:00 PM **End**: 1/2/2017 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Columbus Day **Location**: United States

Start: 10/11/2020 8:00:00 PM **End**: 10/12/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/23/2023 7:00:00 PM **End**: 11/24/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Christmas Holiday (Observed)

Location: United States

Start: 12/25/2016 7:00:00 PM **End**: 12/26/2016 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Labor Day Location: United States

Start: 9/6/2020 8:00:00 PM **End**: 9/7/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Thanksgiving Day Location: United States

Start: 11/22/2023 7:00:00 PM **End**: 11/23/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:15 PM

Subject: Day After Thanksgiving Day

Location: United States

Start: 11/24/2016 7:00:00 PM **End**: 11/25/2016 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Independence Day (Observed)

Location: United States

Start: 7/2/2020 8:00:00 PM **End**: 7/3/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:19 PM

Subject: Veteran's Day (Observed)

Location: United States

Start: 11/9/2023 7:00:00 PM **End**: 11/10/2023 7:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Father's Day Location: United States

Start: 6/20/2020 8:00:00 PM **End**: 6/21/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:42:17 PM

Subject: Memorial Day Location: United States

Start: 5/24/2020 8:00:00 PM **End**: 5/25/2020 8:00:00 PM

Show Time As: Free

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:58:52 PM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: RE: Media around the Abboot rapid Ag test

Our emebrs this week was dallas and I called in favors with lots of tv and print and radio hosts but 1) they have a hurricane there 2) radio is covering rnc and 3) rogue steve schedule kept bumping things around, so we're only hitting one radio in embers. We can do more next week and I asked for Houston so we can do more media I know there.

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Thursday, August 27, 2020 9:24 AM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: RE: Media around the Abboot rapid Ag test

Minus others for deliberation-

I don't believe he has media tomorrow- this antigen test would be good for that time; do socials today, tweets, then discuss tomorrow. Regional media is always available to us easily- we could put him on in Iowa and other non-storm states (who are the focus at the moment). Pennsylvania would be good (Pitt?) and CA.

John 'Wolf' Wagner

Associate Commissioner

From: Miller, Emily < Emily.Miller@fda.hhs.gov Sent: Thursday, August 27, 2020 9:19 AM

To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Wagner, John

<<u>John.Wolf.Wagner@fda.hhs.gov</u>>

Cc: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Rom, Colin < Colin.Rom@fda.hhs.gov>

Subject: RE: Media around the Abboot rapid Ag test

I've asked my team for a quick list of TV outlets and print outlets for Steve to do today. I'd also like to do a Facebook video post about it.

I defer to Wolf for the roll out plan.

-EM

Call/text (b) (6)

From: Shah, Anand < Anand. Shah@fda.hhs.gov>

Sent: Thursday, August 27, 2020 9:15 AM

To: Hahn, Stephen (b) (6) ; Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Miller, Emily

<<u>Emily.Miller@fda.hhs.gov</u>>

Cc: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Rom, Colin < Colin.Rom@fda.hhs.gov>

Subject: RE: Media around the Abboot rapid Ag test

Steve – I am checking with CDRH as to whether they coordinated with OEA or OC on this press release, but I was not aware this was going live when it did. Given the wide interest in these antigen POC tests, we should've had OC level comms.

The test is authorized for use in individuals suspected of COVID-19 with the first 7 days of symptom onset. Similar to other antigen tests, it can be used off-label for screening of asymptomatics not suspected of COVID

From: Hahn, Stephen < SH1@fda.hhs.gov > Sent: Thursday, August 27, 2020 8:32 AM

To: Wagner, John < <u>John.Wolf.Wagner@fda.hhs.gov</u>>; Miller, Emily < <u>Emily.Miller@fda.hhs.gov</u>> **Cc:** Shah, Anand < Anand.Shah@fda.hhs.gov>; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Subject: Re: Media around the Abboot rapid Ag test

What is the format? Anand, did we authorize this test for screening?

Steve

From: John Wagner < John. Wolf. Wagner@fda.hhs.gov>

Date: Thursday, August 27, 2020 at 8:29 AM

To: Stephen Hahn < SH1@fda.hhs.gov>, Emily Miller < Emily.Miller@fda.hhs.gov>

Cc: Anand Shah <Anand.Shah@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Media around the Abboot rapid Ag test

Suggested:



John 'Wolf' Wagner Associate Commissioner

From: Hahn, Stephen < SH1@fda.hhs.gov > Sent: Thursday, August 27, 2020 8:12 AM

To: Miller, Emily < Emily.Miller@fda.hhs.gov; Wagner, John < John.Wolf.Wagner@fda.hhs.gov> Cc: Shah, Anand < Anand.Shah@fda.hhs.gov>; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Subject: Media around the Abboot rapid Ag test

I see the media around this. Isn't this something that we should be making a bigger deal about?

Steve

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:56:48 PM

To. Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Kimberly, Brad

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Keep us posted in real time on interview requests – we can try to do some by phone. I don't think they are key to this story getting to the public because the anchors have an easy read and a visual with the graphics or stores. The print reporters have plenty of material. Let's be sure lots of social media-facebook where moms will read it.

-EM

Call/text (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Sent: Thursday, August 27, 2020 9:37 AM

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Cc: Miller, Emily < Emily. Miller@fda.hhs.gov>; Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

So far just one interview request, but I anticipate every local and national station under the sun will ask for one after they catch wind from the CNN wire and have their morning planning meetings.



Here's the list so far. I will add to it as the morning goes on:

CBS Newspath	For all CBS local stations	Zoom	Today

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











From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Thursday, August 27, 2020 8:51 AM To: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Cc: Miller, Emily < Emily. Miller @fda.hhs.gov >; Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Thanks, Jeremy.

Could you reply-all with a list of requests including outlet, reporter, interview type, deadline, and your recommendation for what FDA SME can do it? Who in CDER has had media training and could be prepped quickly for this topic?

Cheers. Shannon

Shannon P. Hatch

Media Relations Director

Office of Media Affairs Office of External Affairs Mobile: (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov >

Sent: Thursday, August 27, 2020 8:26 AM

To: Hatch, Shannon < Shannon.Hatch@fda.hhs.gov>; Miller, Emily < Emily.Miller@fda.hhs.gov>

Subject: Re: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Starting to get questions from national outlets including one requesting a zoom interview(CBS News) for today. Let me know if we should consider participating in any.

Jeremy Kahn, M.A.

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













From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Date: August 27, 2020 at 4:57:03 AM EDT To: Miller, Emily < Emily. Miller@fda.hhs.gov> Cc: Kahn, Jeremy < Jeremy. Kahn@fda.hhs.gov>

Subject: Fwd: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Emily—Not sure you're on our press release list yet. Here you go...

From: FDA Office of Media Affairs <news@prnewswire.com>

Date: August 27, 2020 at 4:00:34 AM EDT

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers



FOR IMMEDIATE RELEASE August 27, 2020

COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Silver Spring, MD --- The U.S. Food and Drug Administration (FDA) is warning consumers about <u>alcohol-based hand sanitizers</u> that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. The agency has discovered that some hand sanitizers are being packaged in beer cans, children's food pouches, water bottles, juice bottles and vodka bottles. Additionally, the FDA has found hand sanitizers that contain food flavors, such as chocolate or raspberry.

"I am increasingly concerned about hand sanitizer being packaged to appear to be consumable products, such as baby food or beverages. These products could confuse consumers into accidentally ingesting a potentially deadly product. It's dangerous to add scents with food flavors to hand sanitizers which children could think smells like food, eat and get alcohol poisoning," said FDA Commissioner Stephen M. Hahn, M.D. "Manufacturers should be vigilant about packaging and marketing their hand sanitizers in food or drink packages in an effort to mitigate any potential inadvertent use by consumers. The FDA continues to monitor these products and we'll take appropriate actions as needed to protect the health of Americans."

In one recent example of consumer confusion, the FDA received a report that a consumer purchased a bottle they thought to be drinking water but was in fact hand sanitizer. The agency also received a report from a retailer about a hand sanitizer product marketed with cartoons for children that was in a pouch that resembles a snack. Drinking only a small amount of hand sanitizer is potentially lethal to a young child, who may be attracted by a pleasant smell or brightly colored bottle of hand sanitizer.

Hand sanitizer can be toxic when ingested. The FDA continues to see an increasing number of adverse events with hand sanitizer ingestion, including cardiac effects, effects on the central nervous system, hospitalizations and death, primarily reported to poison control centers and state departments of health. For more information, consumers should refer to the FDA's guidelines on <u>safe use of hand sanitizer</u> as well as <u>a question and answer page</u>.

The FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's <u>MedWatch Adverse Event Reporting</u> program (please provide the agency with as much information to identify the product as possible).

The FDA continues to proactively work with manufacturers to recall potentially dangerous hand sanitizer products and is strongly encouraging retailers to remove these products from store shelves and online marketplaces. A <u>list of hand sanitizer products</u> the FDA urges consumers not to use, along with a description for consumers on how to use the list, has been posted to the agency's website, which is being updated regularly.

Media Contact: <u>Jeremy Kahn</u>, 301-796-8671 Consumer Inquiries: <u>Email</u> or 888-INFO-FDA

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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FDA-OC- OMA COMS Aug20P1

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 9:57:41 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hahl

CC: 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]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; 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]; Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: CBS This Morning Prep

Attachments: CBS 8-25-20 interview prep.docx

Dr. Hahn, Attached and below are goals, logistics, questions to expect and suggested talking points for your morning interview.

Purpose: White House wants us to put an end to the back and forth narrative on 35% from press conference and we want you to CP to give people hope that their loved ones in hospital have a better chance of survival.

Three main points to make no matter what questions you get:



Outlet: CBS Morning News

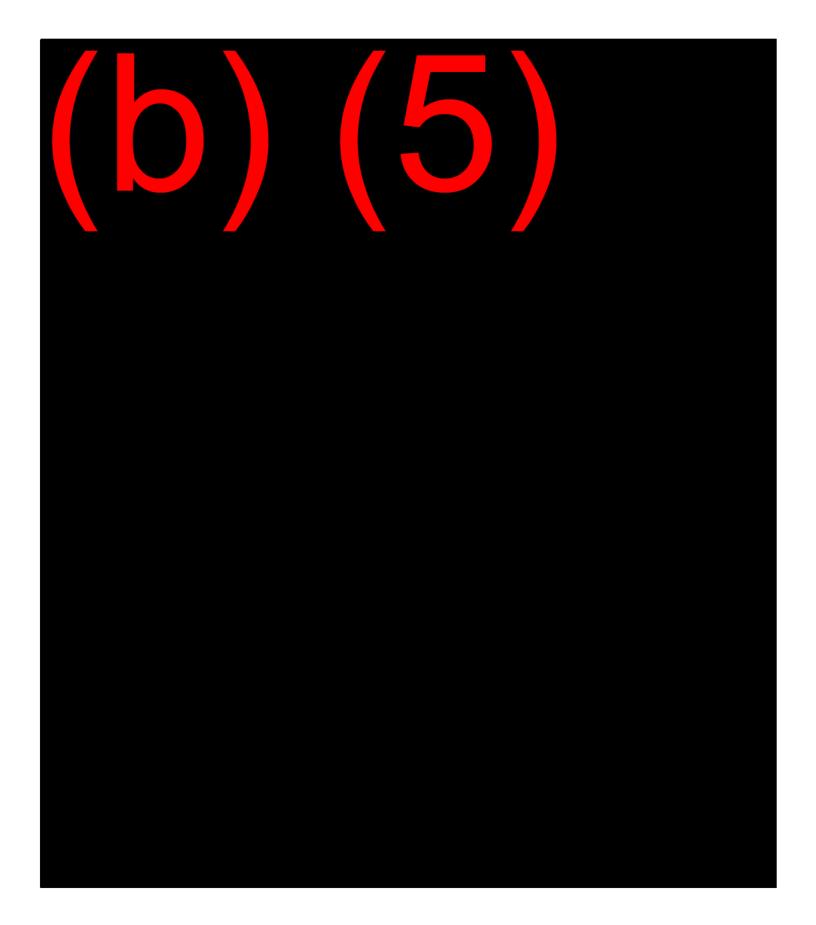
Anchor: Gayle King

Air date: Tuesday 8/25 -- Live at 6am MT/8am ET. Length: 5 minutes

Logistics: CBS is getting a truck and crew to drive to your home. They will arrive at 4am to set up OUTSIDE the house.

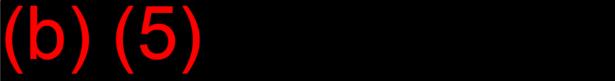
Expected questions with talking points:





Emily Miller FDA Assistant Commissioner for Media Affairs Call/text: (b) (6) **Purpose:** White House wants us to put an end to the back and forth narrative on 35% from press conference and we want you to CP to give people hope that their loved ones in hospital have a better chance of survival.

Three main points to make no matter what questions you get:



Outlet: CBS Morning News

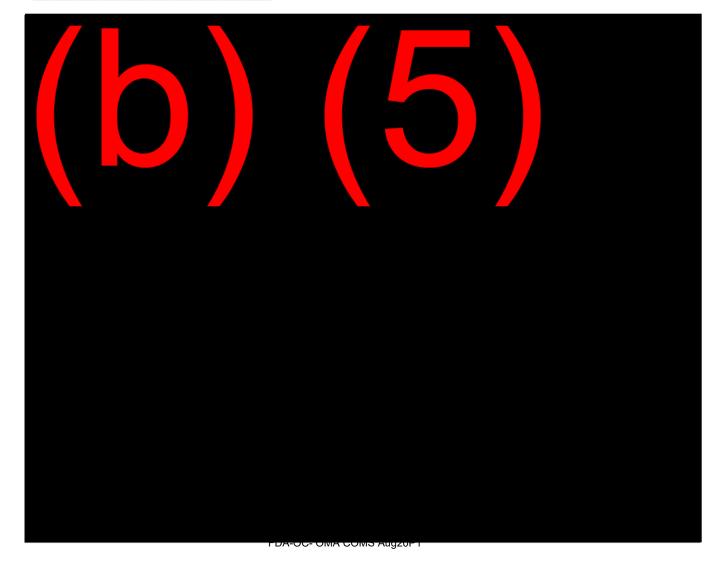
Anchor: Gayle King

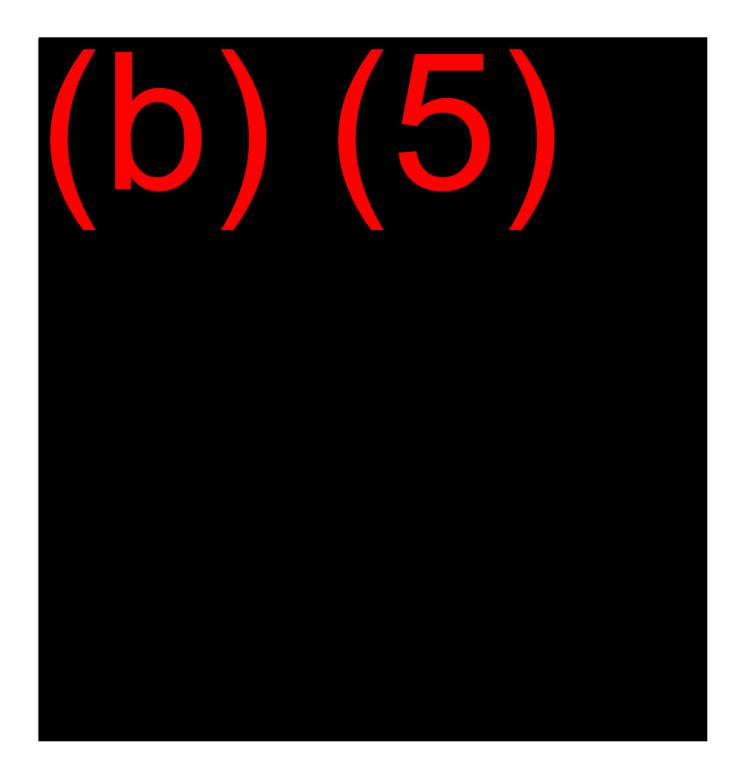
Air date: Tuesday 8/25 -- Live at 6am MT/8am ET. Length: 5 minutes

Logistics: CBS is getting a truck and crew to drive to your home. They will arrive at 4am to set up

OUTSIDE the house.

Expected questions with talking points:





(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 6:35:44 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: RE: Axios on HBO

I already did, that's why he's looking for a better answer ©

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Monday, August 24, 2020 5:52 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Wagner, John < John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: Axios on HBO

Will you go back to him again with us on it and respond suggesting the others?

From: Miller, Emily < Emily.Miller@fda.hhs.gov Date: August 24, 2020 at 5:49:54 PM EDT

To: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov > Cc: Wagner, John < John.Wolf.Wagner@fda.hhs.gov >

Subject: RE: Axios on HBO

He's trying to get an answer he likes! He asked me and I said absolutely not, in light of that horrible interview with POTUS. I said since he wants to do HBO – which I think is great because it has a huge young audience who we can educate- let's do Circus or Real Time. I know both so could pitch them.

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Monday, August 24, 2020 5:46 PM **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Cc: Wagner, John < John.Wolf.Wagner@fda.hhs.gov>

Subject: Axios on HBO

Jonathan Swann wants SH to do Axios on HBO. Apparently, last person to do it was POTUS. He would like to do it. Can you watch Potus version and see your thoughts. Let us know what you recommend. Pls

Thanks,

Keagan

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 10:30:11 AM

To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]

Subject: FW: QUERY — SALON

FYI only below....

-EM

Call/text (b) (6)

From: Miller, Emily

Sent: Wednesday, August 26, 2020 10:30 AM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Subject: RE: QUERY — SALON

Wolf -- The story came out and it's full of inaccuracies. Can someone at HHS ASPA or WH at least on background ask for correction on the facts so this doesn't become the permanent narrative that I was put in just now and undercut the credibility of FDA and Dr. Hahn?

https://www.salon.com/2020/08/26/former-one-america-news-correspondent-emily-miller-gets-senior-fda-post/

If you want, I can list out the specific false info, but top is

1) I was called by White House in May to take this job while I was running a Texas county government coronavirus task force and spokesman for it 2) I started talking to Hahn in June 3) My approval was July 4) My start date was Aug 17th 5) I worked for OAN in 2016 and interviewed Trump many times but have not talked to the president since I last interviewed him a week before the election. 6) I've never met Caputo until I walked in the first day and he got me through the security desk.

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 7:27 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: QUERY — SALON

Let it be. Will only get weirder.

John 'Wolf' Wagner Associate Commissioner

 $\textbf{From: Miller, Emily} < \underline{Emily}.\underline{Miller@fda.hhs.gov} >$

Sent: Tuesday, August 25, 2020 8:44 PM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov >; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov >

Subject: Fwd: QUERY - SALON

The left finally figured out I'm at FDA. See questions below. I actually don't mind having Stephanie answer some questions to take away the sinister narrative.

But I don't want to make decisions on my own press because doctors don't operate on themselves.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Roger Sollenberger <rsollenberger@salon.com>

Date: August 25, 2020 at 6:01:24 PM EDT **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Subject: QUERY — SALON

Hi Emily, and hope you're well!

Wondering if you could answer a few questions about your hire.

Did someone from the administration reach out to you about this position?

Did you speak with Michael Caputo ahead of your hiring?

How do you reconcile your time at a pro-Trump news outlet with your public service employment?

When were you hired? Who was former Acting Asst Commissioner, and where are they now?

Thanks!

Roger Sollenberger Staff Writer, News

(b) (6) (Cell, WhatsApp, Signal)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 9:47:36 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Amin, Stacy

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shuren, Jeff

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: RE: WaPo/LDTs

Stephanie, Can you send us a draft response and then let's go through approval process?

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:43 AM

To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>

Cc: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Miller, Emily < Emily. Miller@fda.hhs.gov>

Subject: WaPo/LDTs

Laurie McGinley/WaPo sent this note to a colleague in my office this AM:

"I would also like to officially request data that I'm told the FDA has that shows that 50 percent of LDTs have problems."

How would you like OMA to proceed?

Stephanie Caccomo

Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 9:30:05 AM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: RE: Financial Times for surrogates

This week. Profile goes out whether we participate or not by Friday or Saturday. (I clear with time zones). I sent this up to you when we got it and didn't get a response so trying to move fast now.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Date: August 26, 2020 at 9:28:19 AM EDT **To:** Miller, Emily <Emily.Miller@fda.hhs.gov> Subject: RE: Financial Times for surrogates

Do they have a timeline/deadline? I'll make the ask; they're not usually favorable to a profile piece at all. Birx would be the biggest hurdle by far.

John 'Wolf' Wagner Associate Commissioner

From: Miller, Emily < Emily. Miller @fda.hhs.gov> Sent: Wednesday, August 26, 2020 9:25 AM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: Financial Times for surrogates

Wolf,

Can you ask HHS and WH if we can ask surrogates to talk to the reporter for the profile? Then if we hear back that it's fair, can we put on Hahn?

Hahn recommends we use surrogates: Shah, Birx, Lynn Wilson, Ramesh Ranen (not sure spelling because he told me by phone but he's a doctor.)

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Date: August 26, 2020 at 9:21:10 AM EDT To: Miller, Emily < Emily.Miller@fda.hhs.gov> **Cc:** Hatch, Shannon < Shannon.Hatch@fda.hhs.gov>, Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov> **Subject:** FT info for surrogates

FT writing a profile of Dr Hahn given how much the FDA is currently in the news. Topics include treatments/vaccines, but also about his leadership style, who he turns to for counsel, and communicating with the public during the pandemic.

Kiran Stacey
Washington Correspondent
Financial Times
Kiran Stacey kiran.stacey@ft.com

Office: +1 202 434 0982 Mobile: +(b) (6)

Stephanie Caccomo

Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 6:35:01 PM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: FW: Qs from Sanjay Gupta's team

I'm not responding to this but for situational awareness, this is gonna dog us until we get SH to say it in public correctly.

-EM

Call/text (b) (6)

From: Kounang, Nadia < Nadia. Kounang@turner.com >

Sent: Monday, August 24, 2020 5:55 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: Re: Qs from Sanjay Gupta's team

Sorry – one other question – during the briefing yesterday, Dr. Hahn said "A 35% improvement in survival is a pretty substantial clinical benefit. What that means is — and if the data continue to pan out — 100 people who are sick with Covid-19, 35 would have been saved because of the administration of plasma" --- Dr. Marks' statement says "the FDA notes that there appears to be roughly a 35 percent relative improvement in the survival rates of hospitalized patients who were treated with higher titer plasma when compared to those hospitalized patients treated with lower titer plasma."

They are saying slightly different things – is there going to be a clarification on Dr. Hahn's statement of 35% improvement in overall survival?

Thanks again.

From: Nadia Kounang < Nadia. Kounang@turner.com >

Date: Monday, August 24, 2020 at 5:02 PM **To:** "Miller, Emily" < Emily. Miller@fda.hhs.gov>

Cc: "Caccomo, Stephanie" < Stephanie. Caccomo@fda.hhs.gov>

Subject: Re: Qs from Sanjay Gupta's team

Got it - thanks for the clarification.

In the questions that we've posed – we'd also like to ask if there was anything that prompted this change in decision making since last week? Our understanding is that last week there was a pause in granting the EUA because of concerns over lack of evidence. Was there any change in thinking or evidence seen that resulted in yesterday's EUA decision?

Thanks.

From: "Miller, Emily" < Emily. Miller@fda.hhs.gov>

Date: Monday, August 24, 2020 at 4:52 PM

To: Nadia Kounang < Nadia. Kounang@turner.com >

FDA-OC- OMA COMS Aug20P1

Cc: "Caccomo, Stephanie" < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Qs from Sanjay Gupta's team

We wanted to clarify that Dr. Marks is referring to hospitalized patients who received the plasma, so the below quote is only different in the two places needed to make that clear. If you can, please try to update with this so people understand who he means. Thanks!

"FDA reviewed data from multiple sources, including over a dozen published studies, as well as the prepublication data from the Mayo Clinic. We also conducted our own analysis of the data from the national Expanded Access Program for COVID-19 convalescent plasma. Note that in the Expanded Access Program, the antibody titer of the plasma given to patients was not known until after patients were treated, potentially reducing any bias. Although the effect size with the administration of COVID-19 convalescent plasma varies somewhat from study to study, likely in part to the different populations treated, the FDA notes that there appears to be roughly a 35 percent relative improvement in the survival rates of hospitalized patients who were treated with higher titer plasma when compared to those hospitalized patients treated with lower titer plasma. Given the safety profile observed, the totality of evidence regarding potential efficacy more than adequately met the 'may be effective' standard for granting an Emergency Use Authorization."

From: Miller, Emily

Sent: Monday, August 24, 2020 4:13 PM

To: Nadia.Kounang@turner.com

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: FW: Qs from Sanjay Gupta's team

We will work on all your questions, as I'm sure you know, we are drowned in media inquires today. Below is an on the record quote below is from Dr. Peter Marks, Director of the FDA Center for Biological Evaluation and Research:

"FDA reviewed data from multiple sources, including over a dozen published studies, as well as the prepublication data from the Mayo Clinic. We also conducted our own analysis of the data from the national Expanded Access Program for COVID-19 convalescent plasma. Note that in the Expanded Access Program, the antibody titer of the plasma given to patients was not known until after patients were treated, potentially reducing any bias. Although the effect size with the administration of COVID-19 convalescent plasma varies somewhat from study to study, likely in part to the different populations treated, the FDA notes that there appears to be roughly a 35 percent relative improvement in the survival rates of patients who were treated with higher titer plasma when compared to those treated with lower titer plasma. Given the safety profile observed, the totality of evidence regarding potential efficacy more than adequately met the 'may be effective' standard for granting an Emergency Use Authorization."

From: Kounang, Nadia < Nadia.Kounang@turner.com >

Sent: Monday, August 24, 2020 1:59 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Cc: Sealy, Amanda < Amanda.Sealy@cnn.com > Subject: Re: Sanjay--FDA EUA decision memo

Thanks for the speedy response. Understood that CBER made the decision.

May we be able to speak with the point person who made the decision in CBER? Whether that is Dr. Peter Marks, or someone else?

In addition, while I understand that Dr. Hahn did not make the review decision, was he involved in the decision process at all? If so, what role did he play?

And even if he wasn't involved in the decision making, did he review any of the data?

And just to make sure – because I didn't see it embedded within the links that you sent – and I may have just overlooked it – but wanted to confirm that this is the EUA that was presented to the FDA:

https://www.fda.gov/media/141481/download

Thanks. Nadia

From: "Caccomo, Stephanie" < Stephanie. Caccomo@fda.hhs.gov>

Date: Monday, August 24, 2020 at 1:42 PM

To: Nadia Kounang < Nadia.Kounang@turner.com > Cc: Amanda Sealy < Amanda.Sealy@cnn.com > Subject: RE: Sanjay--FDA EUA decision memo

Dr. Hahn did not make this review decision, to be clear, our Center for Biologics Evaluation and Research made this decision.

The information we can share is outlined in the request from ASPR and our decision memo.

Stephanie Caccomo

Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (6) (6)

stephanie.caccomo@fda.hhs.gov

From: Kounang, Nadia < Nadia.Kounang@turner.com >

Sent: Monday, August 24, 2020 1:41 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Cc: Sealy, Amanda < Amanda.Sealy@cnn.com > Subject: Re: Sanjay--FDA EUA decision memo

Hi Stephanie -

Hoping you might be able to help us answer this question:

In the FDA's decision making process on yesterday's EUA for convalescent plasma — do you know if the FDA reviewed any additional data beyond what was submitted in the EUA application? If so, what data was that and can that be made available to us? Also, if there was additional information reviewed in the decision making process, do you know if that is information that was also made available to Dr. Hahn and if he reviewed that information?

Much thanks for your help with this.

Best, Nadia Kounang CNN Health

From: Amanda Sealy < Amanda. Sealy@cnn.com >

Date: Sunday, August 23, 2020 at 6:40 PM

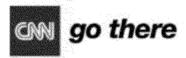
To: "Caccomo, Stephanie" < <a href="mailto:Stepha

Cc: Nadia Kounang < Nadia.Kounang@turner.com > Subject: Re: Sanjay--FDA EUA decision memo

Thank you for this

Amanda Sealy | Senior Producer

Mobile: (b) (6) Desk: +1404-827-3556



From: Stepanie Caccomo < Stephanie. Caccomo@fda.hhs.gov>

Date: Sunday, August 23, 2020 at 6:38 PM **To:** "Gupta, Sanjay" < scalpel@turner.com>

Cc: "amanda.sealy@cnn.com" < Amanda.Sealy@cnn.com>

Subject: Sanjay--FDA EUA decision memo

Sanjay-

Wanted to make sure you had our press release, which links to our decision memo that outlines the data used to make the decision.

https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment
https://www.fda.gov/media/141480/download

Stephanie Caccomo

Media Relations Director

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

(b)(5) DRAFT

(b)(5) DRAFT

(b)(5) DRAFT

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 6:32:54 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Felberbaum, Michael

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

Subject: RE: A statement or tweet?

Agree with Stephanie. The best thing right now would be to put out massive amounts of data. Did anyone get clearance to send out the Mayo link?

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Monday, August 24, 2020 6:01 PM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Miller, Emily < Emily. Miller@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>
Subject: RE: A statement or tweet?

Wolf-

I worry that would further inflame the situation right now. Reporters are very confused about the SOURCE of that data. It's not clear in our documents we posted yesterday.

If we point to a source in the tweet, that might help, but I think saying he's correct without showing the source of that number might not help right now.

Stephanie Caccomo

Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956

stephanie.caccomo@fda.hhs.gov

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Monday, August 24, 2020 5:59 PM

To: Miller, Emily < Emily.Miller@fda.hhs.gov >; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >; Felberbaum,

Michael < Michael. Felberbaum@fda.hhs.gov>

Subject: A statement or tweet?

Can this fit?

(b) (5)

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs U.S. Food and Drug Administration john.wolf.wagner@fda.hhs.gov



Sent from my mobile device

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 9:47:03 PM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Kahn, Jeremy

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]

CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Let's try to do this in the future. I'm adding Brad. Video is the only thing people get their news from anymore and easy. We can use the commissioner or the experts and I can also do them easily. Great idea for pushing media.

I didn't realize hand sanitizer was released. When we get staffed up better, I'm going to have people do clips of news we need to read during the day to see the results of the efforts and what can get us more news.

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Thursday, August 27, 2020 10:09 AM
To: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

I like your suggestion if it's not too heavy of a lift.

Shannon P. Hatch

Media Relations Director

Office of Media Affairs
Office of External Affairs
Mobile: (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov >

Sent: Thursday, August 27, 2020 9:37 AM

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Cc: Miller, Emily < Emily.Miller@fda.hhs.gov; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

So far just one interview request, but I anticipate every local and national station under the sun will ask for one after they catch wind from the CNN wire and have their morning planning meetings.

(b) (5)			
	_	·	•

Here's the list so far. I will add to it as the morning goes on:

CBS Newspath	For all CBS local stations	Zoom	Today

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











From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Thursday, August 27, 2020 8:51 AM

To: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Thanks, Jeremy.

Could you reply-all with a list of requests including outlet, reporter, interview type, deadline, and your recommendation for what FDA SME can do it? Who in CDER has had media training and could be prepped quickly for this topic?

Cheers, Shannon

Shannon P. Hatch

Media Relations Director

Office of Media Affairs Office of External Affairs Mobile: (b) (6)

From: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>

Sent: Thursday, August 27, 2020 8:26 AM

To: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Re: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Starting to get questions from national outlets including one requesting a zoom interview(CBS News) for today. Let me know if we should consider participating in any.

Jeremy Kahn, M.A.

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











From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Date: August 27, 2020 at 4:57:03 AM EDT To: Miller, Emily < Emily. Miller@fda.hhs.gov> Cc: Kahn, Jeremy < Jeremy. Kahn@fda.hhs.gov>

Subject: Fwd: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Emily—Not sure you're on our press release list yet. Here you go...

From: FDA Office of Media Affairs <news@prnewswire.com>

Date: August 27, 2020 at 4:00:34 AM EDT

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers



FOR IMMEDIATE RELEASE August 27, 2020

COVID-19 Update: FDA Warns Consumers About Hand Sanitizer Packaged in Food and Drink Containers

Silver Spring, MD --- The U.S. Food and Drug Administration (FDA) is warning consumers about alcohol-based hand sanitizers that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. The agency has discovered that some hand sanitizers are being packaged in beer cans, children's food pouches, water bottles, juice bottles and vodka bottles. Additionally, the FDA has found hand sanitizers that contain food flavors, such as chocolate or raspberry.

"I am increasingly concerned about hand sanitizer being packaged to appear to be consumable products, such as baby food or beverages. These products could confuse consumers into accidentally ingesting a potentially deadly product. It's dangerous to add scents with food flavors to hand sanitizers which children could think smells like food, eat and get alcohol poisoning," said FDA Commissioner Stephen M. Hahn, M.D. "Manufacturers should be vigilant about packaging and marketing their hand sanitizers in food or drink packages in an effort to mitigate any potential inadvertent use by consumers. The FDA continues to monitor these products and we'll take appropriate actions as needed to protect the health of Americans."

In one recent example of consumer confusion, the FDA received a report that a consumer purchased a bottle they thought to be drinking water but was in fact hand sanitizer. The agency also received a report from a retailer about a hand sanitizer product marketed with cartoons for children that was in a pouch that resembles a snack. Drinking only a small amount of hand sanitizer is potentially lethal to a young child, who may be attracted by a pleasant smell or brightly colored bottle of hand sanitizer.

Hand sanitizer can be toxic when ingested. The FDA continues to see an increasing number of adverse events with hand sanitizer ingestion, including cardiac effects, effects on the central nervous system, hospitalizations

and death, primarily reported to poison control centers and state departments of health. For more information, consumers should refer to the FDA's guidelines on <u>safe use of hand sanitizer</u> as well as <u>a question and answer</u> page.

The FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's <u>MedWatch Adverse Event Reporting</u> program (please provide the agency with as much information to identify the product as possible).

The FDA continues to proactively work with manufacturers to recall potentially dangerous hand sanitizer products and is strongly encouraging retailers to remove these products from store shelves and online marketplaces. A <u>list of hand sanitizer products</u> the FDA urges consumers not to use, along with a description for consumers on how to use the list, has been posted to the agency's website, which is being updated regularly.

###

Media Contact: <u>Jeremy Kahn</u>, 301-796-8671 Consumer Inquiries: Email or 888-INFO-FDA

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 4:11:39 PM

To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel] FW: FOR REVEIW AND CLEARANCE: OCI Quote for DOJ Release-- Indivior Misbranded Drugs

I don't understand why some press officers send to me to review and some to you/Shannon/Stephanie. How can I get that into a system with less of me holding up things because I'm in meetings?

-EM

Subject:

Call/text (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:04 PM

To: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Cc: Arnold, Nathan <Nathan.Arnold@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Miller,

Emily < Emily. Miller@fda.hhs.gov>

Subject: FOR REVEIW AND CLEARANCE: OCI Quote for DOJ Release-- Indivior Misbranded Drugs

FOR REVIEW AND CLEARANCE

Office: OCI

Subject: OCI Quote for DOJ Release- Indivior Misbranded Drugs

Materials: Press Release

Planned Release Date: 8/26 12pm Deadline for Comments: 8/25 EOD

Driving Event: Guilty Plea



Department of Justice

United States Attorney's Office Western District of Virginia

FOR IMMEDIATE RELEASE August 26, 2020 Western District of Virginia Contact: Brian McGinn Public Affairs Specialist brian.mcginn@usdoj.gov

Opioid Manufacturer Indivior's Former Medical Director Pleads Guilty In Connection With Drug Safety Claims ABINGDON, VIRGINIA – Timothy Baxter, the former medical director of Indivior, pleaded guilty today in U.S. District Court in Abingdon to a one-count information charging him with causing the introduction into interstate commerce of the opioid drug Suboxone Film, which was misbranded in violation of the Federal Food, Drug, and Cosmetic Act. Indivior's former chief executive officer, Shaun Thaxter, pleaded guilty to a similar charge last month.

Baxter was the medical director of Indivior (formerly known as Reckitt Benckiser Pharmaceuticals) from 2000 until he left the company in May 2016. Indivior and one of its subsidiaries have agreed to pay \$600 million to resolve their criminal and civil liability, with the subsidiary pleading guilty to making false statements relating to health care matters. Indivior's former parent company, Reckitt Benckiser Group, previously paid \$1.4 billion to resolve its liability.

Suboxone Film is a drug approved for use by recovering opioid addicts to avoid or reduce withdrawal symptoms while they undergo drug-addiction treatment. Suboxone and its active ingredient, buprenorphine, are powerful and addictive opioids.

According to court documents, Baxter admitted that an Indivior employee he supervised sent inaccurate drug-safety information to the Massachusetts Medicaid agency, which is called MassHealth, in 2012. More specifically:

- Baxter was familiar with the issue of unintended pediatric exposure meaning children taking drugs by accident and worked on it over several years.
- In 2012, Indivior had a contractor collect data on unintended pediatric exposure to buprenorphine drugs, with Baxter approving the project.
- In October 2012, an Indivior medical affairs manager who Baxter supervised met with MassHealth, and urged it to expand its coverage of Suboxone Film. In connection with the meeting, the medical affairs manager asked Indivior's contractor collecting data on unintended pediatric exposure for data on Massachusetts. The contractor sent the data to the medical affairs manager. The data showed that other buprenorphine drugs not Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts. But the medical affairs manager changed the data, to make it appear that Suboxone Film had the lowest rate of unintended pediatric exposure in Massachusetts, and emailed the altered, inaccurate data to MassHealth. The medical affairs manager forwarded the email to Baxter, stating, "I hope this helps us get some movement" on expanding MassHealth coverage of Suboxone Film.
- Then in November 2012, the medical affairs manager emailed MassHealth an incomplete graph that intentionally omitted more data on unintended pediatric exposure that was arguably unfavorable to Suboxone Film. Baxter did not receive the email; but in another context, Baxter approved of using this incomplete graph.
- Then the following quarter, the medical affairs manager received still more data showing that other buprenorphine drugs had lower unintended pediatric exposure than Suboxone Film in Massachusetts. The medical affairs manager withheld the data from MassHealth, and later stated in a speech at an Indivior corporate conference that her rationale was "don't ask, don't tell."

- In December 2012, MassHealth announced that it would expand coverage of Suboxone Film for patients with children under the age of six.
- With Baxter's approval, Indivior sent a correction letter to MassHealth in December 2015. By that time, the company had come under government investigation. FAUSA QUOTE

VA-OAG QUOTE

FDA QUOTE

OCC DRAFTED

"Opioid addiction and abuse is a serious public health crisis and addressing it is one the FDA's highest priorities. Providing misleading information about drugs used to treat opioid addiction could ultimately exacerbate the problem by making these treatments more difficult to obtain," said Catherine Hermsen, Assistant Commissioner of the FDA's Office of Criminal Investigations. "We will continue to work with the Department of Justice to investigate and hold accountable those who devise and participate in fraud schemes to the detriment of the public health."

HHS QUOTE

POSTAL QUOTE

The case against Baxter is being prosecuted by attorneys from the U.S. Attorney's Office for the Western District of Virginia and the Department of Justice's Civil Division, including Albert P. Mayer, Randy Ramseyer, Kristin L. Gray, Joseph S. Hall, Janine M. Myatt, Garth W. Huston, Carol Wallack, Charles J. Biro, and Matthew J. Lash. The investigation of Baxter was handled by the FDA's Office of Criminal Investigations; the Virginia Medicaid Fraud Control Unit; the United States Postal Service- Office of Inspector General; and the U.S. Department of Health and Human Services - Office of Inspector General. Assistance was provided by representatives of the FDA's Office of Chief Counsel.

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 4:10:41 PM

To: 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]

CC: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Michael, before we lose you (crying), can you write out for us the clearance process currently for anything that comes out of our office? Then we can make sure to incorporate that into our newer system but keep your institutional knowledge here when you're gone!

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:07 PM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov> **Cc:** Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Thank you for clarifying.

From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:07 PM

To: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Miller, Emily < Emily.Miller@fda.hhs.gov>
Cc: Hatch, Shannon < Shannon.Hatch@fda.hhs.gov>; Wagner, John < John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

It does have a consumer focus, but it is a press release and has a quote from SH. Press releases go to ASPA for clearance.

From: Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:02 PM **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Cc: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>; Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Felberbaum,

Michael < Michael. Felberbaum@fda.hhs.gov>

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

I think this is something we would just give HHS a heads up in the night note, right Michael? Not clearance of the PR?

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:00 PM

To: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Cc: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>; Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

It's an important press release on hand sanitizer that is being packaged into food and bev and child food packaging.

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:59 PM
To: Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Is it a press release or a consumer alert? If consumer alert, they don't go to HHS.

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 2:27 PM

To: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov >

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Keagan— See below- Wolf said press releases for consumer things don't go to HHS or WH. You're good with us releasing this with his approval only?

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 2:24 PM

To: Miller, Emily < Emily.Miller@fda.hhs.gov

Cc: Hatch, Shannon < Shannon.Hatch@fda.hhs.gov

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

My suggested edits-(b) (5)

Check me if I'm wrong, but these go out as 'consumer' notices and don't require ASPA/HHS clearance, only ours.

John 'Wolf' Wagner

Associate Commissioner

From: Wagner, John

Sent: Tuesday, August 25, 2020 2:17 PM

To: Miller, Emily < Emily.Miller@fda.hhs.gov

Cc: Hatch, Shannon < Shannon.Hatch@fda.hhs.gov

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Not two min ago I got press paper saying it's being delayed a day or so- I'll forward that.

I sent one update to you this morning- adding (6) (5) as a descriptor of the packaging.

John 'Wolf' Wagner

Associate Commissioner

From: Miller, Emily < Emily. Miller @fda.hhs.gov >

Sent: Tuesday, August 25, 2020 2:15 PM

To: Wagner, John < John. Wolf. Wagner @fda.hhs.gov > Cc: Hatch, Shannon < Shannon. Hatch @fda.hhs.gov >

Subject: RE: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Wolf-

Have you gotten approval for this yet? It's getting late in the day to send out again so may move to tomorrow.

-EM

Call/text (b) (6)

From: Miller, Emily

Sent: Tuesday, August 25, 2020 10:36 AM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Subject: FOR APPROVAL ASAP -- Press Release- Hand Sanitizer Packaging

Wolf,

Please look at the attached press release and make edits as you like. Keagan and Hahn approved. Per our new system, you'll made any edits and send to lawyers and HHS and WH for approval. Then send back to me the final to get out today.

You'll see I've changed style so it's more simple language that media can repeat that public can understand. I've also cut out a lot of backstory and used links instead so reporters will not get drowned in long release. We want to get this out today because it's really important.

Thanks,

-EM

Call/text (b) (6)

From: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 10:14 AM
To: Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: FOR CLEARANCE -- Press Release- Hand Sanitizer Packaging

Clean copy attached. This is ready for further clearance.

Thanks,

--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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 9:45:46 AM

To: Caccomo, 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]

Subject: RE: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Great. Keep everything in one document. I'll do big picture strategy and then we break that down into how we can reach each key stakeholder audience.

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:45 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Sounds like a plan. If you don't mind, I'll assign starting the doc (and formatting) to the press officers assigned to cover vaccines so they can make it all fancy while waiting for your input.

And we'll get it into Sharepoint so everyone can access it!

Stephanie Caccomo

Media Relations Director

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Desk: 301.348.1956

stephanie.caccomo@fda.hhs.gov

Celi: (b) (6)

From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:27 AM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Thank you for this.... The request came from Keagan because I'm doing the strategy part and she wants Wolf shop to coordinate.

This content is great! Stephanie, can you start a document with this in it and we'll start building out a strategy because I need to get a draft by Friday.

I'm not sure when I'm supposed to stop and think through it so I may calendar myself to do it!

-EM

Call/text (b) (6)

From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:10 AM

To: Miller, Emily < Emily.Miller@fda.hhs.gov; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>

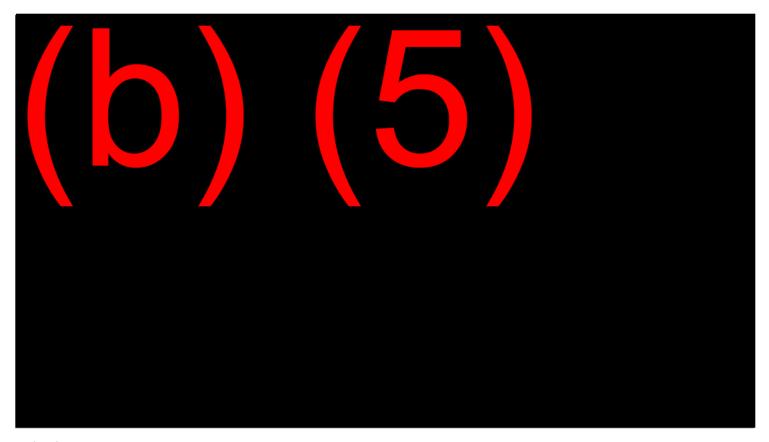
Subject: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Hi both,

On the OEA leadership check-in today, Wolf asked that each OEA office provide by Thursday to Jason Strachman-Miller some ideas for making an eventual rollout of a COVID vaccine successful (based in part on some lessons learned from the plasma rollout).

Emily, I believe you said you were working on some sort of strategic comms plan on this, so you may want to let Wolf know that's in the works. I also know that ASPA is working on a full-on public education campaign.

I'm sharing a few notes, but since I'll be out, would one of you be able to close the loop on this Thursday ask?



Thanks,

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) michael.felberbaum@fda.hhs.gov













<u>Please fill out this information and return to:</u> Emily Miller at either

E-mail: millerej@state.gov *or* fax 202-647-3344

Your Name:
Network and show:
Work Phone:
Cell Phone:
E-Mail:
Anchor name:
Producer name (if applicable):
Interview - remote or in person:
Unilateral or pool crew:
Number of video cameras:
Number of Production staff (if applicable):
Producer and crew arrival time and which entrance (C St or 23 rd):
Live or taped:
Interview start time:
Interview length:
Time interview airs live- all in EST time:
Date/time for State Department official transcript release:
Other outlets where interview will air:
Other guests on the show and order of guests:
Current ratings estimate:
What are the expected questions and/or tonics for the interview?

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 1:46:34 PM

To: 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]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]

Subject: TV show logistics

Attachments: STATE- Morning shows sign in.doc

This is the sign in sheet for TV interviews back in the day. A lot of these things are different now with Covid and zoom but gives you a good starting point to create email drafts to send to tv outlets to get all their info and cut and paste into memos.

-EM

Call/text (b) (6)

From: Emily Miller (b) (6)

Sent: Tuesday, August 25, 2020 1:30 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Fwd: Powell in the morning

Emily Miller

Call/Text: (b) (6)

----- Forwarded message ------

From: <(unknown sender)>

Date: Mon, Dec 27, 2004 at 4:35 PM Subject: Powell in the morning

To: <gina.garcia@nbc.com>, Susan LaSalla (E-mail) <Susan.LaSalla@nbcuni.com>, <hsp@cbsnews.com>,

<adam.a.belmar@abc.com>

Hi all-

Please send back the attached sheet as soon as you can so I can get things set up on this end.

We're doing the interview on the Mezzanine level of the C Street lobby (aka the Flag location).

If you are sending a crew or producer who does not have State credentials, please call? to organize an escort into the building.

NBC- We have a high chair here for the Secretary. I'll put the audio in your crew's hands since you know it is a little echo-y in the lobby.

Here's the order for tomorrow. let me know if there are any problems with this lineup.

06:20-06:25 TAPED CBS "The Early Show"<?xml:namespace prefix = o ns = "urn:schemas-microsoft-com:office:office" />
06:20-06:35 TAPED ABC "Good Morning America"
06:40-06:45 TAPED CNN "American Morning"
06:50-06:55 TAPED Fox News Channel "Fox and Friends"
07:00-07:00 LIVE NBC "Today Show"

Emily Miller

Deputy Press Secretary

Department of State

Phone: 202-647-9728

Fax: 202-647-3344

Mobile: (b) (6)

International Mobile: (b) (6)

Blackberry e-mail: millerej@dos.osis.gov

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 11:49:47 AM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.Cl

Subject: RE: WSJ article?

They are strong right wing ed board so not surprising. But still I cant read it?

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 11:48 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: WSJ article?

I'm a little surprised by their 'positive' coverage thus far....

John 'Wolf' Wagner

Associate Commissioner

From: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Tuesday, August 25, 2020 11:48 AM

To: Wagner, John < John. Wolf. Wagner @fda.hhs.gov >; Caccomo, Stephanie < Stephanie. Caccomo @fda.hhs.gov >

Subject: RE: WSJ article?

I am blocked by paywall. Do we have a WSJ account.

SH referenced this to me this morning and thought it was great so I assume he had a hand in it, but I didn't know what he was talking about...

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 11:33 AM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: WSJ article?

https://www.wsj.com/articles/the-fdas-good-plasma-decision-11598310767?mod=hp_opin_pos_1

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 10:25:56 AM

To: Hahn, Stephen [SH1@fda.hhs.gov]

CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: Jonathan Swan HBO

Sir, I put together the media coverage of the Swan HBO interview with Pres. Trump (5) (5)

I can call Showtime Circus show or HBO Bill Maher as (b) (5) to reach.

(b) (5)

Axios's Jonathan Swan is the latest interviewer to leave Trump grasping on TV

Jonathan Swan reveals the simple secret to exposing Trump's lies: basic follow-up questions

<u>Jonathan Swan's Face Is the 2020 Meme We Needed -- During his viral Trump interview, the Axios reporter's pained expressions said it all.</u>

Trump's Axios interview was a disaster.

Journalist's gobsmacked reactions during Trump interview are Twitter's too

Social media reacts to Trump's 'shocking' Axios interview with Jonathan Swan on HBO

Trump Collapses Under Pressure of Extremely Basic Follow-Up Questions About COVID-19

Fact-checking 22 claims from President Trump's Axios interview with Jonathan Swan

Psychiatrist as Fly-On-The-Wall at Trump's Axios Interview

The Axios Interview Showed Us an Important Threshold for the President

Emily Miller

Call/Text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 7:36:30 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; 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]

Subject: RE: ///flagging/// FDA Media Inquiry: Food Fraud and Imports, Reuters (David Sherwood), 8/27

Good with me. Wolf?

-EM

Call/text (b) (6)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 7:36 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>

Subject: Re: ///flagging/// FDA Media Inquiry: Food Fraud and Imports, Reuters (David Sherwood), 8/27



Stephanie Caccomo

Media Relations Director

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: Miller, Emily < Emily.Miller@fda.hhs.gov> **Date:** August 26, 2020 at 7:21:24 PM EDT

To: Cassell, Peter < Peter. Cassell@fda.hhs.gov >, Wagner, John < John. Wolf. Wagner@fda.hhs.gov >

Cc: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >, Hatch, Shannon < Shannon.Hatch@fda.hhs.gov >, Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov >, Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov > Subject: Re: ///flagging/// FDA Media Inquiry: Food Fraud and Imports, Reuters (David Sherwood), 8/27

How will the background part be communicated? Will it be quoted and who is attribution?

If it's on background and can be quoted, we need to be sure commissioner office is aware of it. If it's just informative, then just make sure of lawyers clearance.

Thanks

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Cassell, Peter < Peter. Cassell@fda.hhs.gov>

Date: August 26, 2020 at 6:55:59 PM EDT

To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >, Hatch, Shannon < Shannon. Hatch@fda.hhs.gov >,

Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >

Subject: ///flagging/// FDA Media Inquiry: Food Fraud and Imports, Reuters (David Sherwood), 8/27

Hello,

The below response was cleared by OFPR and ORA. This is ready to go to OCC (or if you would prefer to wait until it comes back from OCC), please let me know if you have any comments/concerns/edits.

Thanks! -Pete

FDA Media Inquiry

Reporter: David Sherwood

Outlet: Reuters

Subject: Food Fraud and Imports

Deadline: 8/27 (COB)

<u>Storyline:</u> In the course of their reporting, the reporter has spoken with several food fraud experts, including some based in the United States, who warn that it is exceedingly easy to "game" the food inspection system and slip potentially dangerous and or falsely labeled food into countries like the United States. From a food security, or food defense, standpoint, these experts claim loopholes, lack of effective enforcement and increasingly complex global food chains make it remarkably easy to breach the countries defenses and cause damage and suffering.

<u>Question:</u> Reuters is interested in the FDA's comment on these allegations. Does the FDA agree? How widespread is food fraud, and what are the risks? What specifically is the United States doing to prevent these kinds of breaches?

Response:

Written response:





Additional background:



Peter Cassell

Press Officer

Office of Media Affairs Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-6537

Cell: (b) (6)
Peter.Cassell@fda.hhs.gov











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 7:38:11 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Shah, Anand

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]

Subject: RE: Found "breakthrough"

It was also in the tweet from WH Press secy account announcing the event.

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, August 27, 2020 2:09 PM

To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: RE: Found "breakthrough"

Thank you, Wolf for tracking this down.

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Thursday, August 27, 2020 2:04 PM

To: Shah, Anand <<u>Anand.Shah@fda.hhs.gov</u>>; Lenihan, Keagan <<u>Keagan.Lenihan@fda.hhs.gov</u>>

Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: FW: Found "breakthrough"

This is what I thought- it was something unrelated to FDA or even HHS it appears.

John 'Wolf' Wagner

Associate Commissioner

From: Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>

Sent: Thursday, August 27, 2020 2:00 PM

To: Wagner, John < John. Wolf. Wagner @fda.hhs.gov>

Subject: Found "breakthrough"

Wolf,

I searched our materials. There was no mention of "breakthrough" in FDA comms.

I did find the word mentioned once in the president's remarks:

https://www.whitehouse.gov/briefings-statements/remarks-president-trump-press-briefing-august-23-2020/

THE PRESIDENT: Thank you very much. And it's good to see you all. Hope you had a great weekend at your convention. And we're going to have a great convention coming up, and I look forward to it.

But before I discuss a very historic breakthrough in our fight against the China virus, I'd like to provide an update on the recent wildfires in California and the storms in the Gulf of Mexico.

Bessy Guevara

Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration

Bessy.Guevara@fda.hhs.gov











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 9:28:12 AM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: RE: Attending OMA staff meetings

Okay got it. Do you want him on the press officers call? I really need to fill slots at that too because today is

(b) (6)

Is there anyone in your

department who can move over to any of these slots for a couple months while we battle so much incoming? Stephanie and I alone just can't do it all.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Date: August 26, 2020 at 9:21:08 AM EDT

To: Miller, Emily <Emily.Miller@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Attending OMA staff meetings

Jason is my assistant as well as staff for Sandy. He gathers things for me and keeps me somewhat organized. We have a weekly OMA staff call (you should be on going forward) each tues morning. Given when you started and what was going on, there was no need to push you into it previously. All we do is go over staff stuff with each director (ops, digital, media, outreach, etc)

John 'Wolf' Wagner Associate Commissioner

From: Miller, Emily < Emily. Miller@fda.hhs.gov> Sent: Wednesday, August 26, 2020 9:18 AM

To: Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: Fwd: Attending OMA staff meetings

Wolf - I don't know who is who yet so can you tell me what this is about? Also I haven't had time yet to organize meetings with my staff so for now I'm just getting on their own team calls When I can that are three times a week. Hoping to organize this into a system as soon as possible.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Strachman-Miller, Jason < Jason.Strachman-Miller@fda.hhs.gov>

Date: August 26, 2020 at 9:15:29 AM EDT **To:** Miller, Emily < Emily.Miller@fda.hhs.gov **Subject:** Attending OMA staff meetings

Good morning Emily,

After the OEA leadership meeting, Wolf wrote me and said I should attend the weekly OMA staff meetings. Is that OK by you? Do you mind sending along an invite.

Thanks, Jason

Jason Strachman Miller, MA

Writer Editor

Office of Editorial and Creative Services Office of External Affairs U.S. Food and Drug Administration Office: 240.402.1745

Cell: (b) (6)

Jason.Strachman-Miller@fda.hhs.gov











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 9:45:01 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: Wolf/Emily--Flagging outstanding SH interview requests

Can you do one document that is rolling with interview requests? I can send you a sample one I have done for other jobs so you get the gist of it. We need to always track and be able to see what's out there. Will send when I put out this fire.

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:29 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: RE: Wolf/Emily--Flagging outstanding SH interview requests

Two more things to add!!

Forgot to add below:



Stephanie Caccomo

Media Relations Director

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: Caccomo, Stephanie

Sent: Monday, August 24, 2020 10:08 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov >; Hatch, Shannon < Shannon.Hatch@fda.hhs.gov >

Subject: Wolf/Emily--Flagging outstanding SH interview requests

Flagging the requests we've received and status. plus my own recs.

FYI, we secured morning media time JUST Thursday/Friday. But we also have the 3:30 timeslot at WH studio on Thursday. WE could fit in additional studio time Friday when he is taping NASDA at HHS if needed, would just need to hold down asap.

- Maria Bartiromo—Stephanie handling
- Scheduling this for Thursday AM; hope to have mobile van at his DC apt
- NPR: 10 minutes to talk about the CP decision
- o (b) (5)
- They are open to either join a live taping OR a pre-taped
- Jonathan Swan/Axios+HBO show—Jonathan told me he'd want 30 minutes to chat. Could go anywhere to tape
- o (b) (5)
- EMILY will you follow up, or want me to?
- Sinclair—10 min, per WH request. Stephanie handling
- Scheduled for Thursday, at WH EEOB
- Nextstar—per WH request, will get details; Stephanie handling
- Can fit in Thursday at WH; will finalize in AM
- WHITE HOUSE LOCAL DMAS—Stephanie and OMA team handling
- Dallas + Corpus Christi—I'll start working with our team to pitch/get these lined up for radio/TV

Others that reached out post CP announcement

- Today Show
- Brian Mudd, WJNO Florida (a repeat, he did super well before, but I'd prioritize WH requests over this)
- Squawk Box, CNBC

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Stephanie Caccomo

Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 5:13:31 PM

To: Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]

RE: FOR REVIEW AND CLEARANCE: COVID-19 Press Release- Hand Sanitizer Packaging Subject:

Thanks... I'd like it to be more clear on what is legal, not legal and what we can do about it when we catch it.

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Sent: Monday, August 24, 2020 5:12 PM To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: FOR REVIEW AND CLEARANCE: COVID-19 Press Release- Hand Sanitizer Packaging

We have one line in at the moment, see highlight below. I'll ask what else we can add.



--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











From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Sent: Monday, August 24, 2020 5:09 PM

To: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: FOR REVIEW AND CLEARANCE: COVID-19 Press Release- Hand Sanitizer Packaging

Can you please check with the lawyers if we can add some enforcement language into this?

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Sent: Monday, August 24, 2020 5:05 PM To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Subject: RE: FOR REVIEW AND CLEARANCE: COVID-19 Press Release- Hand Sanitizer Packaging

Thanks Emily!



Hope this helps.

--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











From: Miller, Emily < Emily. Miller @fda.hhs.gov> Sent: Monday, August 24, 2020 4:33 PM

To: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: FOR REVIEW AND CLEARANCE: COVID-19 Press Release- Hand Sanitizer Packaging

Can we find out where this is coming from-like outside the US? It's so appalling to put in baby food containers etc and it might be criminal if it is a US company (not sure, now a lawyer) but if it's outside the US, I'd like to include that info if that's possible.

I'm editing now and wil send to Wolf and Keagan and back to you to get to lawyers.

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov >

Sent: Monday, August 24, 2020 10:54 AM To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: FOR REVIEW AND CLEARANCE: COVID-19 Press Release- Hand Sanitizer Packaging

Emily- FOR REVIEW AND CLEARANCE

Office: CDER

Subject: COVID-19 Hand Sanitizer Packaging

Materials: Press Release

Planned Release Date: 8/24 or 8/25 Deadline for Comments: 8/24 ASAP Driving Event: Consumer Safety Issue

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 2:33:25 PM

To: Emily Miller (b) (6)

Fwd: Links Subject:

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Mulieri, Chris < Charles. Mulieri@fda.hhs.gov>

Date: August 26, 2020 at 2:30:11 PM EDT

To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Subject: Links

Emily:

Bio: https://www.fda.gov/about-fda/fda-organization/emily-miller

Leadership Profiles page: https://www.fda.gov/about-fda/fda-organization/fda-leadership-profiles

Chris

Chris Mulieri, PMP

Director, Web & Digital Services Office of External Affairs U.S. Food and Drug Administration Tel: 301-796-8864 / Cell: chris.mulieri@fda.hhs.gov











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 4:42:47 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

RE: Press Paper clearance ***attaching current press officer SOP Subject:

I appreciate your efforts but I need a one page sheet that shows me who is doing what clearance below me so I can adjust what happens above me. It's much more complicated than I'm getting into now, but one of you needs to take all this data into one page max.

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:41 PM To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Subject: RE: Press Paper clearance ***attaching current press officer SOP

Should I find a later time on your calendar? We'd really like to talk through this with you asap.

Stephanie Caccomo

Media Relations Director

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Desk: 301.348.1956

stephanie.caccomo@fda.hhs.gov

----Original Appointment----

From: Miller, Emily < Emily. Miller @fda.hhs.gov> **Sent:** Tuesday, August 25, 2020 4:41 PM

To: Caccomo, Stephanie

Subject: Declined: Press Paper clearance ***attaching current press officer SOP

When: Wednesday, August 26, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where:

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 8:39:34 PM

To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

Subject: Fwd: Bloomberg story text

See below but do it tomorrow morning from Steve account not now

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Date: August 25, 2020 at 6:28:17 PM EDT

To: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Bloomberg story text

I would consider amplifying some of his quotes on tweets from Spox and link story

John 'Wolf' Wagner

Associate Commissioner

Office of External Affairs U.S. Food and Drug Administration john.wolf.wagner@fda.hhs.gov



Sent from my mobile device

From: Miller, Emily <Emily.Miller@fda.hhs.gov>

Date: August 25, 2020 at 6:05:17 PM EDT

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>, Hahn, Stephen < SH1@fda.hhs.gov>, Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Bloomberg story text

Here is the link. Okay to social media it from all accounts? Will tramp down a lot of critics.

https://www.bloomberg.com/news/articles/2020-08-25/fda-s-hahn-vows-to-stick-to-the-science-amid-vaccine-pressure

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: **(b) (6)**

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Date: August 25, 2020 at 5:23:39 PM EDT

To: Miller, Emily <Emily.Miller@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Bloomberg story text

Yes. A very good result. I don't think anyone else could have pulled it off.

John 'Wolf' Wagner Associate Commissioner

From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 5:09 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>
Subject: Bloomberg story text

This is the text of the Bloomberg story that will hit the wire soon. I think it reads really genuine and honest which is not normal in media and hopefully business community will read this and feel better about FDA impartiality than it did from the nonsense swirl Sunday.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Drew Armstrong (BLOOMBERG/ NEWSROOM:) < darmstrong17@bloomberg.net>

Date: August 25, 2020 at 4:58:36 PM EDT **To:** Miller, Emily < Emily . Miller@fda.hhs.gov >

Subject: Story text

(Bloomberg) --

The U.S. Food and Drug Administration is facing controversy after its commissioner, Stephen Hahn, substantially overstated the benefits of an experimental therapy for Covid-19 patients.

In a press conference with Trump, Hahn said the therapy — blood plasma from recovered patients — could save 35 of every 100 people who would have died. Those high-profile remarks were incorrect, and they were repeated by others in the Trump administration. Hahn late Monday clarified some of what the data on blood plasma actually show.

But the episode has raised questions about how the agency will review a vaccine, as well as its scientific independence as Trump's reelection hinges on his response to the virus.

Bloomberg spoke to Hahn by phone. The conversation has been edited and condensed for clarity.

Bloomberg: You've taken a lot of criticism and scrutiny over the 48 hours since the press conference with the president. What's that been like?

Hahn: It's been a challenge. The thing that has been the most challenging, has been trying to get out the public health message. A lot of things have happened in the last two weeks regarding convalescent plasma. And I think the convergence of all of those things created the impression of political interference. That's the biggest concern because I have complete trust in the scientists at FDA.

Bloomberg: You're a highly trained doctor and researcher. But your quote at the press conference about 35 out of 100 people being saved by this therapy when the benefit is far less, how did that mistake happen? (The data the FDA looked at was two categories of plasma — a higher dose, and a lower one. It only compared how one group did against another, now how great the benefit was versus a placebo.)

Hahn: I was trying to do what I do with patients, because patients often understand things in absolute terms versus relative terms. And I should've been more careful, there's no question about it. What I was trying to get to is that if you look at a hundred patients who receive high titre, and a hundred patients who received low titre, the difference between those two particular subset of patients who had these specific criteria was a 35% reduction in mortality. So I frankly did not do a good job of explaining that.

Bloomberg: What was the internal reaction at the FDA to your error?

Hahn: We've had frank discussions about it. We're sorting those out. I am going to have to correct that and I'm going to have to accept the fact that I made a mistake and own it. I think that's the first start.

Bloomberg: Other people in the administration have taken your misstatement and repeated it. Have you asked them to take those statements down or correct them?

Hahn: I have not spent time talking to others in the administration about this. I did have a conversation with [Health and Human Services] Secretary [Alex] Azar about this. I feel like my job is just to clarify from an FDA point of view, what we meant. The White House is aware of my attempts to clarify the situation. But other than that I have not had any additional conversations.

Blomberg: What happened in your conversation with Azar?

Hahn: We just discussed this issue and making sure that the right information is out there.

Bloomberg: It's an incredibly political time, and people are already inclined to distrust what they hear. Do you worry that the public perception of the FDA has been hurt by this?

Hahn: Absolutely, I worry about that. I can only hope that being honest and straightforward lessens that impact. But as you mentioned, we're in an incredibly politicized time, and these are really difficult concepts to explain to the American people.

At the end of the day, I know my patients never cared about relative versus absolute benefits. They just wanted to understand if the juice is

worth the squeeze. The totality of data was in support of a promising benefit and safety.

Bloomberg: Do you worry making blood plasma more widely available will make it harder to get patients into clinical trials? If I'm a Covid-19 patient, why would I sign up for a trial and maybe get a placebo?

Hahn: Yeah, I do worry about it. We aren't going to be able to twist doctor's arms to enroll their patients. The gold standard of a randomized trial would be incredibly helpful here. We may find that the benefit goes away with more data. If that happens, we're going to reevaluate our EUA.

Bloomberg: President Trump has been a proponent of drugs like hydroxychloroquine, even after the FDA pulled back an emergency authorization when it was found not to be helpful. Do you feel that political pressure and that it could happen with other products?

Hahn: Yeah, I'm aware of it. I've listened to all the conversations. But what I tell internally our folks is they need to make the decisions based upon the data. I have not reversed one of their decisions, nor do I intend to unless I think it's absolutely wrong. So, yeah, I listen to it, but it's not going to change what we do.

Bloomberg: There was a report by Reuters that Peter Marks, who leads the group in the FDA that reviews vaccines, would resign if the agency approved a vaccine without enough safety and efficacy data. Did he say that?

Hahn: Peter did not say that to me. But it wouldn't surprise me that that is accurate.

Bloomberg: What would you, personally, do if you felt like you were being asked to rubber-stamp a vaccine?

Hahn: I'm not going to speculate, other than to tell you that it would not be okay for me and I would not participate in any decision that was made any on anything other than the science.

Bloomberg: There was another report, by Axios, that White House adviser Peter Navarro told some FDA officials that ""You are all Deep State and you need to get on Trump Time," accusing the agency of slowing down work to hurt the president politically. Did that happen?

Hahn: I was not present for that comment. I have heard it reported. I just don't know when or if occurred. What I can tell you is that I feel very strongly that the 17,000-plus FDA employees are true professionals. None of them wants to delay getting medical products into the hands of Americans.

Bloomberg: What level of evidence is needed to get a vaccine into people's hands, for example on an emergency basis to an at-risk group? More than for blood plasma, or for hydroxychloroquine?

Hahn: Remember a vaccine is given to healthy individuals. So it's a different clinical circumstance than giving plasma to hospitalized, sick patients. That has to be considered in the decision making.

Bloomberg: Do you think the FDA has more political independence because of its public health role? Should it? And has that changed at all?

Hahn: The FDA is often caught in the middle of a lot of different conversations. It's magnified because we're in a significant public health crisis. And what FDA does in a public health crisis is to try to get medical products to address that crisis. FDA always feels under a microscope with respect to its decisions. It's never gonna make all people happy.

Bloomberg: Do you think the FDA should be an independent agency, like the Federal Reserve, instead of part of the Health and Human Services Department?

Hahn: I hadn't really thought about that.

Bloomberg: It might sound good right now.

Hahn: I hadn't really thought about that. I think it's worth consideration, because of the issues that we're talking about. So I don't really have a stance on it because I haven't put much thought into it. I don't want to rush into giving you an opinion about it.

Blomberg: Have you grappled with the possibility that you'll have vaccine data right before, or right after, election day, and how you'll handle that?

Hahn: Of course I've thought about it. We've been thinking about this, frankly, since the spring and early summer.

It's why we put out vaccine guidance on June 30th, because we wanted to put our marker down. We wanted folks to know what we're going to need to see from a safety, efficacy, patient, or volunteer population point of view. It's why we feel so strongly about having a vaccine advisory committee review the data with us. And we spent a lot of time internally thinking about how can we adjust our processes to make sure it's all hands on deck when we receive the data.

Bloomberg: Do you think it's realistic to have a vaccine in the hands of patients by then?

Hahn: I'm a cancer doctor. I tell my patients I don't have a crystal ball, and I most definitely do not have a crystal ball here. I don't think it would be prudent for me to speculate on that because I just don't know.

Drew Armstrong Senior Editor, Health Care Bloomberg News 212.617.8933 (o)

(b) (6) @ArmstrongDrew (t)

POLITICAL BRIEFING PAPER

EVENT:	LIVE RADIO INTERVIEW: "THE CHRIS SALCEDO SHOW"		
DATE:	Tuesday, Sept. 11		
TIME:	9 - 9:30 a.m. CT		
LOCATION:	Residence. Studio call-in phone: (b) (6)		
PURPOSE:	Talk to DFW area conservatives on 9/11 and priorities of keeping Texas red and DC controlled by Republicans in order to have strong economy and job growth. Salcedo is promoting it as the second edition of "Ted Talks."		
OUTLET	WBAP News Talk 820 AM, Dallas/Fort Worth		
HOST:	Chris Salcedo, Morning Show Host		
CONTACT:	Chris cell: (b) (6)		
AIR DATE:	Live		
STAFF:	Emily (b) (6)		
TOPICS:	9/11 anniversary and progress on war on terror, then will open to caller questions on the campaign.		
Prepared by:	Emily Miller (b) (6)		

POLITICAL BRIEFING PAPER

EVENT:	TAPED TV INTERVIEW: ABC News "This Week" and "Nightline"			
DATE:	Friday, Oct. 18			
TIME:	3:10 3:30 pm CT			
LOCATION:	Stockyards			
PURPOSE:	ABC News will be using this interview to air stories on your race across their major shows, so this is an opportunity to reach a wide audience to encourage voting on Monday.			
REPORTER	Paul Faris, Anchor and Senior Correspondent			
CONTACT:	Jessica Hopper (b) (6)			
AIR DATE/OUTLETS	The interview will air on "This Week" on Sunday and be the lead story on Monday night on "Nightline". Soundbites may be used on other shows.			
STAFF:	Emily (b) (6)			
BACKGROUND	This will be a very newsy interview on the race topics such as why a Democrat is doing well statewide in Texas, your different views on immigration/border security and how Pres. Trump coming Monday helps or hurts in Texas. Paula is interviewing Beto on Saturday so you will should emphasize his leftist			
Prepared by:	policy positions are out of touch with Texans and his lack of accomplishments. Emily Miller (b) (6)			

Paula Faris is an Anchor and Senior National Correspondent at ABC News. Previously, she was the co-anchor of "Good Morning America"'s weekend edition, as well as a co-host of ABC's "The View".

While at ABC News, the Emmy-Award winning journalist has reported on a wide-array of topics, from the 2018 Royal Wedding in Windsor, England, to the 90th Annual Academy Awards, the 2017 Inauguration of President Donald Trump, the World Cup in Brazil and the New England Patriots "Deflategate" scandal, as well as the Republican National Convention. In October 2017, Faris garnered headlines for an exclusive interview with former White House Press Secretary, Sean Spicer.

Previously, she sat down exclusively with controversial Kentucky clerk, Kim Davis, who made global headlines for refusing to issue marriage licenses to same-sex couples. She's hosted "The Oscars Backstage" at the 87th Academy Awards. And, has interviewed everyone from former Secretary of State Hillary Clinton and Senator Bernie Sanders to Vice President Joe Biden, Reese Witherspoon, Dwayne "The Rock" Johnson, Tiger Woods, Steph Curry, the Duggars and the cast of 'Star Wars'.

POLITICAL BRIEFING PAPER

Faris came to ABC News after spending over 10 years working for TV affiliates in Chicago, Cincinnati and Dayton. She began her career behind the scenes, shooting, editing and producing.

A native of Jackson, Michigan, Faris graduated Cum Laude from Cedarville University (OH) and married her college sweetheart in 2000. She resides in New York with her husband and their three young children.

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 1:45:14 PM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; 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]

Subject: Interviews briefing memo

Attachments: Chris Salcedo BP Sept. 11.docx; ABC Paula Faris interview BP (1).docx

Like I did last night for CBS, I want us to give briefing memos the night before interviews for SH.

The major purpose for doing these is for us to do critical thinking of what outlets we want to put him on and why. Always asking ourselves, who is the target audience and what do we want to tell them. That's the purpose.

The second purpose is for the various offices and people who have part of Commissioner's days and content know what's happening and when and what he's saying so they can be included.

I dug into my cloud drives but my State dept ones are on a hard drive somewhere in a storage locker but these attached are some I used for Cruz campaign to show you my concept of what I want our memos to Commissioner and all internal to use. (IDK why Cruz liked these weird tables so we won't do that, but use what I did last night as a template style.)

You'll see from Faris one that if there's more to say than the basic answers at the top, it's done on separate pages so if he wants to dig deep, he can.

And we can use Salcedo info this week- small world.

Please share with the rest of the team so they do the leg work to get it to you to me.

-EM

Call/text (b) (6)

From: Emily Miller (b) (6)

Sent: Tuesday, August 25, 2020 1:30 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: briefing paper sample

Emily Miller

Call/Text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 7:35:06 PM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 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: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]

Subject: RE: CP EUA rollout--news stories

I would appreciate if that quote could get given to them.

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 7:30 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: RE: CP EUA rollout--news stories

If, the only way we can push back as they are attempting to pin anything on Emily, is to be quoted, we ask Dr H if the following could be attributed to him:



John 'Wolf' Wagner

Associate Commissioner

From: Miller, Emily < Emily <a href="mailto:Emily Emily Emily <a href="mailto:Emily <a href="mai

To: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>; Wagner, John < John.Wolf.Wagner@fda.hhs.gov>; Lenihan,

Keagan < Keagan.Lenihan@fda.hhs.gov >; Shah, Anand < Anand.Shah@fda.hhs.gov >

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: Re: CP EUA rollout--news stories

What's their deadline? What are they aiming to write narrative wise? It's odd to have both of the biggest print reporters want to do an historical story unless someone is pushing a narrative. We need to think this through if it's not tonight response.

Emily Miller

Text/call: (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Date: August 26, 2020 at 6:33:38 PM EDT

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>, Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>, Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: CP EUA rollout--news stories

Hi both-

Sheila Kaplan and Katie Thomas at NYT want to talk about the CP EUA rollout.

Laurie McGinley at WaPo pinged me off the record earlier today to ask about the comms as well. I told Laurie off the record that our comms go through multiple rounds of clearances.

I do not recommend we do any interviews, but instead would like to share this, attribution TBD:



Thoughts?

Stephanie Caccomo

Media Relations Director

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: Sheila Kaplan (b) (6)

Sent: Wednesday, August 26, 2020 4:34 PM

To: Caccomo, Stephanie <<u>Stephanie.Caccomo@fda.hhs.gov</u>>; Miller, Emily <<u>Emily.Miller@fda.hhs.gov</u>>; Katie Thomas katie.thomas@nytimes.com

Subject: Seeking interview with Ms. Miller

Dear Ms. Caccomo and Ms. Miller:

Katie Thomas and I are writing a story that follows up on the agency's release of the EUA for convalescent plasma. We'd like to talk to Ms. Miller about the preparation of the materials for the announcement, including Dr. Hahn's remarks. Also, we'd like to ask Ms. Miller to clarify the previously reported 2015 home invasion incident.

Thank you, Sheila and Katie

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 7:32:10 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: RE: I have no staff

I don't have any staff available to tell me missing pieces in the memo Steve wants tonight. The interviews yet to be scheduled, the prep paper for tomorrow morning, etc. Should I send a half baked one or not one at all?

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, August 27, 2020 6:46 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Subject: Re: I have no staff

Does SH want you speaking to those reporters?

From: Miller, Emily < Emily.Miller@fda.hhs.gov **Date:** August 27, 2020 at 6:42:46 PM EDT

To: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>, Wagner, John < John.Wolf.Wagner@fda.hhs.gov>

Subject: I have no staff

(b) (6)

I have the to do the responses to the NYT/WP/AP and the new daily email to SH tonight and no one to tell me this is cleared or not. I'll keep moving and doing my job but I want you to know that I'm flying blind. I don't know anyone under their level and they didn't fill for themselves as I asked. We don't have a deputy, sr. advisor and missing one meager so that's all we got.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Call/text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 8:37:00 PM

To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

CC: 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]

Subject: Re: Bloomberg interview

(b) (5)

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Date: August 25, 2020 at 7:24:05 PM EDT **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael Felberbaum@fda.hhs.gov>, Caccomo, Stephanie

<Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: Bloomberg interview

Just seeing this.

Let me see what I can do.

From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Date: August 25, 2020 at 6:07:57 PM EDT

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael Felberbaum@fda.hhs.gov>, Caccomo, Stephanie

<Stephanie.Caccomo@fda.hhs.gov>
Subject: Bloomberg interview



 $\underline{https://www.bloomberg.com/news/articles/2020-08-25/fda-s-hahn-vows-to-stick-to-the-science-amid-vaccine-pressure}$

Emily Miller

FDA	Assistant	C	ommissioner	for	Media	Affairs
	TEDDIDUCTIO	$\overline{}$	OIIIIIIIIIIIIIII	101	1110010	

Text/call: (b) (6)

<u>Please fill out this information and return to:</u> Emily Miller at either

E-mail: millerej@state.gov *or* fax 202-647-3344

Contact Name:
Organization:
Work Phone:
Cell Phone:
E-Mail:
Host name:
Engineer name:
Producer arrival time and entrance:
Engineer arrival time and entrance:
Air Date and time (include replay):
Information on amount and location of stations:
Does this air in Washington? What time and station?
Transcript Release Day/Time:
Can we have an electronic copy of the show to post on the web? If so, who is the contact to
get the file?
Other outlets where interview will air:
What are the expected questions and/or topics for the interview?

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 1:38:38 PM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; 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]

Subject: Interview prep

Attachments: STATE- radio in person sign in.doc

Found this in the archives! When I was drowning in interview requests and prepping the secy, I asked each outlet to fill out their own information so I could cut and paste into the briefing memos. I think was super organized since I found different ones for TV, print and radio. But for us, I think just take the type of questions in these and make a template email for yourself and send it to the reporter and say, hey, can you answer these questions and send back? That cuts back on going back and forth on logistical issues with them.

-EM

Call/text (b) (6)

From: Emily Miller (b) (6)

Sent: Tuesday, August 25, 2020 1:33 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Fwd: interview sign in

radio sign in Emily Miller

Call/Text: (b) (6)

----- Forwarded message ------

From: <(unknown sender)>

Date: Tue, Jan 11, 2005 at 10:59 AM

Subject: interview sign in

To: Juan Williams (E-mail) < jwilliams@npr.org>

send back ASAP

Emily Miller

Deputy Press Secretary

Department of State

Phone: 202-647-9728

Fax: 202-647-3344

Mobile: (b) (6)

International Mobile: (b) (6)

Blackberry e-mail: millerej@dos.osis.gov

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

8/26/2020 2:32:27 PM Sent:

To: Mulieri, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=298e49cef842458dad2312551ffdf184-Charles.Mul]

Subject: Re: Links

Bless you!

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Mulieri, Chris < Charles. Mulieri@fda.hhs.gov>

Date: August 26, 2020 at 2:30:11 PM EDT To: Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Links

Emily:

Bio: https://www.fda.gov/about-fda/fda-organization/emily-miller

Leadership Profiles page: https://www.fda.gov/about-fda/fda-organization/fda-leadership-profiles

Chris

Chris Mulieri, PMP

Director, Web & Digital Services Office of External Affairs U.S. Food and Drug Administration Tel: 301-796-8864 / Cell: (b) (6) chris.mulieri@fda.hhs.gov













(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 7:30:52 PM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: for AM media

I made it clear last week that we send prep memos the night before to him for all interviews. She already drafted the FT one but we need one for radio. His office just asked for it.

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Thursday, August 27, 2020 7:29 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: for AM media

No. Let them know that there is not one.

My understanding is that Stephanie had been having prep calls with him and doing the briefing verbally rather than in writing. We haven't stood up our new process to prepare memos in advance. We're going to do that first with the FT interview.

Shannon P. Hatch

Media Relations Director

Office of Media Affairs
Office of External Affairs
Mobile: (b) (6)

From: Miller, Emily < Emily <a href="mailto:Emily Emily Emily <a href="mailto:Emily <a href="mai

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov >; Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Subject: FW: for AM media

Did anyone send a briefing paper up to Steve for his morning call? If not, I'll let his office know there is not one.

-EM

Call/text (b) (6)

From: Copeland, Jakea < Jakea. Copeland@fda.hhs.gov >

Sent: Thursday, August 27, 2020 7:26 PM

To: Miller, Emily < Emily.Miller@fda.hhs.gov >; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >; Olivarria, Frank < Frank.Olivarria@fda.hhs.gov >; Sheehy, Janice < Janice.Sheehy@fda.hhs.gov >

Subject: RE: for AM media

Hi Emily,

Are there any talkers or background for this interview?

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Date: August 27, 2020 at 6:30:36 PM EDT

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >, Olivarria, Frank < Frank.Olivarria@fda.hhs.gov >, Sheehy,

Janice <Janice.Sheehy@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>

Cc: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov >, Rom, Colin < Colin.Rom@fda.hhs.gov >, Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: for AM media

Pls include in SH evening media note

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Sent: Thursday, August 27, 2020 6:29 PM

To: Olivarria, Frank < Frank. Olivarria@fda.hhs.gov >; Sheehy, Janice < Janice. Sheehy@fda.hhs.gov >; Copeland, Jakea < Jakea. Copeland@fda.hhs.gov >

Cc: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Rom, Colin < Colin.Rom@fda.hhs.gov>; Wagner, John < John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily < Emily.Miller@fda.hhs.gov>

Subject: for AM media

Only scheduled interview:

8am-8:10am ET, Sam Malone, Houston TX, live radio interview. SH should call (b) (6)

Stephanie Caccomo

Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE)

Sent: 8/25/2020 9:33:31 AM

To: Hahn, Stephen [SH1@fda.hhs.gov]; 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]; Marks, Peter

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: TRANSCRIPT: CBS News Interview 8/25

Folks- I'm working on getting my team to transcribe and post on website the interviews by Commissioner to put us inline with other federal agencies and departments. Once we figure out a system for it, we can build it out to do all leadership too. Please let me know if you have opinions on how we do this going forward.

For today, this is the CBS transcript below. Feel free to forward to anyone else who would be interested to read it.

On-air Media Interview on Convalescent Plasma Emergency Use Authorization

Date: August 25, 2020
Outlet: CBS This Morning

FDA Expert: Stephen Hahn, MD, FDA Commissioner

Anthony Mason, CBS This Morning: FDA Commissioner Steven Hahn says politics did not play a role in the decision to give doctors the go-ahead for a possible coronavirus treatment. The FDA issued an Emergency Use Authorization for a convalescent plasma treatment Sunday. It uses convalescent plasma from coronavirus survivors that contains antibodies to treat patients battling COVID-19. The therapy had shown potential, but research is still underway.

Gayle King, CBS This Morning: Now this announcement came just one day after President Trump tweeted this: "The deep state or whoever over the FDA's making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd election day." Dr. Hahn joins us now for an interview that you'll see only on CBS this morning. Dr. Hahn, it's good to see you again. Thank you for so much for joining us this morning. I'm thinking it's been quite a year

Dr. Hahn, FDA: Good morning, Gayle. Really appreciate the opportunity.

Gayle King: We're really glad you're here. I'm thinking it's been a real head-spinning 48 hours for you starting with that tweet where the President seemed to be taking your agency to task. Cut to you standing next to the President announcing this breakthrough treatment and emergency authorization of plasma treatment that many people have been using—at least 70,000 people have been using. So, some people say the optics either look like politics or pressure. What do you say about that?

Dr. Hahn: So, first thing I'd like to say is that I personally could have done a better job—and should have done a better job—at that press conference explaining what the data show regarding convalescent plasma. I can assure the American people that this decision was made based upon sound science and data.

We have shown—or the Mayo Clinic convalescent plasma program has shown—that there are promising efficacy data as well as safety associated with plasma. As you mentioned, over 70,000 Americans were treated on this program. These data totally support the Emergency Use Authorization that we issued and we'd been working on this for three or four weeks. We were only waiting for additional validation data, but as you pointed out, we're going to continue to get data. And as we've done with any other authorization, we will update that decision as new data come. But the professionals

and scientists at the FDA independently made this decision and I completely support them. I think it's a good one for American patients and providers.

Gayle King: But I think the problem is, or the issue, Dr. Hahn is that it was made the day before the Republican Convention. So, people say the timing seems a little cowinkydink [sic] and you're saying "No, there's no need to think that there's anything awry here" is what you're saying.

Dr. Hahn: So, the timing was totally based on when we got the data. You probably know that there were reports in the media that there's been some back and forth with external stakeholders—folks at the NIH, but also internally—about what data we needed to see to justify an Emergency Use Authorization. That, combined with the fact that the Mayo Clinic expanded access program was timed to end this week. We felt that having the additional data, which we received last week and early this weekend, and having the time to analyze it, plus the fact that we wanted to maintain availability of plasma for patients and doctors, that led to the timing of this weekend. And those are the facts, Gayle.

Gayle King: The other thing that's raising a couple of eyebrows is that at that announcement, the President and yourself announced that it was reducing deaths by 35%. Top scientists today are wondering where you got that data from. How does that square?

Dr. Hahn: Thanks for the opportunity. And we're putting out additional information to support the emergency use authorization. So, the way this works is that we looked at the Mayo Clinic data. The Mayo Clinic identified a group of patients—certain patients that it looked like the antibodies benefited them the most. We asked for additional validation data that came in, which supported that—meaning that comparing those patients who got high concentrations of antibodies, versus though that those that got low concentrations of antibodies. When you look at those data—the survival benefit between those two groups—it's the relative benefit of 35%. And as I mentioned, I could have done a better job of explaining that at the press conference yesterday.

Gayle King: Was the authorization given, Dr. Hahn, before the clinical trials had taken place? There was some concern about that as well.

Dr. Hahn: There are ongoing clinical trials, and unfortunately they're not accruing like we'd like them to. Of course, FDA completely supports clinical trials performance because at the end of the day, clinical trials—particularly randomized clinical trials—provide gold standard information. Just let me make this clear Gayle: the data that we need, which is a risk benefit assessment for an emergency use authorization, were met by the data that we received and that we had. And the other advantage of this is that it allows patients to have access to it while those trials are accruing. The last point I'd like to make, Gayle, is that there's a great demand for this. Doctors are ordering this for patients around the country. As Americans recover from COVID-19, it would be absolutely great for them to consider donating plasma to meet that demand.

Gayle King: It's also frightening, doctor, that we just heard on the news this morning, that someone who had COVID-19 that it's come back again. How concerned should we be about that?

Dr. Hahn: So, Gayle, as you probably know, throughout this pandemic, we've been learning a lot about the disease. We still continue to believe that the immunity that one has is long lasting, but those data still aren't completely in. We have to follow patients to figure out how long the immunity lasts. And I think there's a lot of data coming in about that. So, I think the jury's still out with respect to that from a science and medicine.

Gayle King: I know, Steve, there seems to be a lot of "jury's still out" when it comes to this disease. Is the relationship with you and the President okay? He seemed to take a couple of pot shots at you from time to time. Do you think you have his support?

Dr. Hahn: I feel like I enjoy a very good relationship with the President. I spoke to him several times this weekend. You know, he wants us to be focused on the urgency of the situation and moving things forward. And I have great faith in the

17,000 FDA employees who are terrific scientists, doctors, and nurses that were going to do that and move it forward for the American people. That's our promise to them.

Gayle King: All right. Dr. Hahn, thank you so much for taking the time this morning. I know you've got a lot on your plate.

Dr. Hahn: Thank you, Gayle.

Gayle King: We'll talk to you another time, I'm sure.

Emily Miller
FDA Assistant Commissioner for Media Affairs
Call/text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 7:30:09 PM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.Cl

Subject: RE: EMILY: SH NIGHTLY COMMS PREP NOTE-Friday, Aug. 27

These are great. Can you resend in a copy that has the attachments so I can forward to SH and company? Also if you don't have the embers one, ask someone on staff since Stephanie must have had someone else working on it.

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Thursday, August 27, 2020 7:15 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: EMILY: SH NIGHTLY COMMS PREP NOTE-Friday, Aug. 27

See my changes below.

Shannon P. Hatch Media Relations Director

Office of Media Affairs
Office of External Affairs
Mobile: (b) (6)

From: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Thursday, August 27, 2020 7:09 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Cc: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: RE: EMILY: SH NIGHTLY COMMS PREP NOTE-Friday, Aug. 27

I highlighted below where I need more info on this for body of email. If I don't hear back from either of you, then I'll send him with the highlights of unknowns.

-EM

Call/text (b) (6)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Thursday, August 27, 2020 6:24 PM
To: Miller, Emily < Emily.Miller@fda.hhs.gov
Cc: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: EMILY: SH NIGHTLY COMMS PREP NOTE-Friday, Aug. 27

Press releases:

1. Broadening EUA for remdesivir to include all hospitalized patients

Timing: After action takes place tomorrow or may slip due to clearance of other materials

2. Approving first long-acting human growth hormone

Timing: After action takes place tomorrow

3. Approve first-of-a-kind automated insulin delivery system for use in young pediatric patients

Timing: Monday, time TBD

SH MEDIA SCHEDULED:

Sam Malone, radio, AM1070 Houston, "The Answser," Live at 8am ET—topic: EUA on CP and vaccine development education

SH FUTURE MEDIA:

Saturday- Kiran Stacy, Financial Times, profile on you, scheduled for 2pm

OUTSTANDING INTERVIEW REQUESTS

- NBC, Today Show Anchor?
- AP Matt Perrone -- tick tock of PC rollout
- NYT Sheila Kaplan tick tock of PC rollout (deadline moved to noon Friday)
- Wash Post about tick tock of rollout
- Jason Whitely, WFAA Dallas TV from White House (embers) and Emily knows his show well no time on schedule this week, will try next week
- Jonathan Swan/Axios + HBO --Told him not this week.

Interview requests that OMA will follow-up with reporters to get more details:

- Brian Mudd, radio, WNJO (will discuss topic interest)
- Maria Bartiromo- Fox Business (will discuss topic interest)

TWEETS SCHEDULED:

- 1. Topic: LUNGevity Foundation launching lung cancer patient research project in collaboration with FDA Content: The LUNGevity Foundation will announce the launch of a new study in collaboration with FDA Oncology Center of Excellence titled, "Understanding the Lung Cancer Patient Experience in the Real-world Setting (Project PEER)". The goal of Project PEER is to understand the lung cancer patient experience, outside of the clinical trial setting and irrespective of stage or histology. FDA will be quoted in a third-party press release.
- 2. Topic: FDA issuing 29th batch of product-specific guidances

Content: FDA will publish its 29th batch of product-specific guidances (PSGs). PSGs provide recommendations for developing generic drugs and generating the evidence needed to support Abbreviated New Drug Application approval, thereby helping to streamline generic drug product development by industry and application assessment by FDA. This batch of 36 PSGs contains 19 new PSGs, including guidances for 27 drugs with no approved generics.

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 10:56:11 PM

To: Broderick, Brianna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2403f4adae453ca6efd28044ddef37-BRODERICKB]

Palmer, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group CC:

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1efe882d2038426faf0ecb4c8bbbe020-PALMERK]; Bess, Demetrice

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0868cf02e2f43faae1205287a521a27-Demetrice.B]

Subject: Re: OCC Onboarding Briefing

I didn't know in advance, but Hahn office put on my calendar a meeting with him at 11a tomorrow. Are you able to see my other meeting times to know when I can do the ethic's lawyer meeting? I know it's important.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Broderick, Brianna < Brianna Broderick@fda.hhs.gov>

Date: August 24, 2020 at 3:00:53 PM EDT

To: Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Palmer, Kelly <Kelly.Palmer@fda.hhs.gov>, Bess, Demetrice <Demetrice.Bess@fda.hhs.gov>

Subject: OCC Onboarding Briefing

Emily,

Another onboarding briefing with the Office of Chief Counsel was set up for you for tomorrow at 11:00AM. I am hoping that day/time will work for you.

Thanks, Brianna

Brianna Broderick

OTS Customer Service Satisfaction Survey

HHS, Food and Drug Administration

Office of Operations, Office of Talent Solutions

Office: 301-796-7751 | Mobile: (b) (6)

Brianna.broderick@fda.hhs.gov

www.fda.gov/jobs



(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 9:29:16 AM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Kimberly, Brad

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: 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]; Thorpe, Valarie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]

Subject: RE: CBS morning

This is awesome!!!

I love the formatting! I'll leave to you to get posted to website.

We need to find out who wants to get email transcripts of his interviews internally.

For now, I'll email it in body to SH, Keagan, Wolf, Marks, Shah and let them forward to whoever else needs it.

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:27 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>

Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>

Subject: RE: CBS morning

I'm attaching the transcript. Will work with Brad, Chris, and team to explore our options of getting this up on the web. Let me know if you see any errors that stand out. As with all our materials, I'll make sure this is copyedited/proofed before posted to FDA.gov.

Shannon P. Hatch

Media Relations Director

Office of Media Affairs
Office of External Affairs
Mobile: (b) (6)

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:15 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >; Caccomo, Stephanie

<<u>Stephanie.Caccomo@fda.hhs.gov</u>>; Thorpe, Valarie <<u>Valarie.Thorpe@fda.hhs.gov</u>>; Hatch, Shannon

<Shannon.Hatch@fda.hhs.gov>

Subject: RE: CBS morning

You know my goal is to reach real people and they are on Facebook- not Twitter. But you know the govt policies and such so whatever you can do so people can hear from him directly. He was really given an open platform to speak today!

Shannon is sending us all the final transcript. Can we get that posted online web?

When we have it, let's decide what we all think are most key lines to pull out for various twitter accounts.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Date: August 25, 2020 at 8:47:30 AM EDT

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov >, Miller, Emily < Emily. Miller@fda.hhs.gov >

Cc: Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov >, Caccomo, Stephanie <<u>Stephanie.Caccomo@fda.hhs.gov</u>>, Thorpe, Valarie <<u>Valarie.Thorpe@fda.hhs.gov</u>>

Subject: RE: CBS morning

Apologies... I meant Spox and Steve. Not Media.

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: Wagner, John < John. Wolf. Wagner@fda.hhs.gov >

Sent: Tuesday, August 25, 2020 8:47 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>

Subject: RE: CBS morning

I think his own account as well. But, Spox and media for certain.

John 'Wolf' Wagner

Associate Commissioner

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 8:46 AM To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Wagner, John < John. Wolf. Wagner @fda.hhs.gov>; Felberbaum, Michael < Michael. Felberbaum @fda.hhs.gov>;

Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >; Thorpe, Valarie < Valarie. Thorpe@fda.hhs.gov >

Subject: RE: CBS morning

So, I understand what you're asking for on Facebook, and we have a standard policy of not amplifying media entities on Facebook or our agency-level US FDA account on Twitter.

There's two reasons for this. 1) It sets a precedent that could cause media outlets to detect favoritism one way or the other. For instance, if we're only amplifying one or two outlets and not others. In DoD, we were taught that you shouldn't do for one what you don't do for all.

And 2) this is not part of standard good practices of operating a government social media account.

Right now, your best options are to amplify this on Twitter on Spox or Media, which I'm actively working on.

Brad Kimberly

Director, Social Media

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Tel: 240-402-1002 | Cell: brad.kimberly@fda.hhs.gov













From: Miller, Emily < Emily. Miller@fda.hhs.gov> Sent: Tuesday, August 25, 2020 8:40 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Wagner, John < John. Wolf. Wagner @fda.hhs.gov>; Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>;

Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: CBS morning

Can you post the whole interview on Facebook? Etc?

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Kimberly, Brad < Brad.Kimberly@fda.hhs.gov>

Date: August 25, 2020 at 8:38:13 AM EDT To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Wagner, John < John.Wolf.Wagner@fda.hhs.gov>, Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov>,

Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Subject: RE: CBS morning

Just now seeing this. I'll try to find it.

I can't cut down third-party sites for clips due to copyright laws, but if it exists on the Internet, we can certainly link to it from either Spox or Steve.

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: Miller, Emily < Emily.Miller@fda.hhs.gov> Sent: Monday, August 24, 2020 10:44 PM

To: Kimberly, Brad < Brad.Kimberly@fda.hhs.gov>

Cc: Wagner, John < John. Wolf. Wagner@fda.hhs.gov >; Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >;

Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Subject: CBS morning

Brad / cbs just said they have a live feed on Twitter and fb so if you can put that on Steve or media site or my site tomorrow I think it will let us best capture. Only 5 min so your prob won't cut down later for clips

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 4:40:53 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: Declined: Press Paper clearance ***attaching current press officer SOP

Start: 8/26/2020 8:30:00 AM **End**: 8/26/2020 9:00:00 AM

Show Time As: Busy

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

8/26/2020 1:01:01 PM Sent:

To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Felberbaum, Michael

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

So true! Yes!

-EM

Call/text (b) (6)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 1:00 PM

To: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

Nope, you're right.

Brad Kimberly

Director, Social Media

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Tel: 240-402-1002 | Cell: brad.kimberly@fda.hhs.gov













From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:56 PM

To: Kimberly, Brad Kimberly@fda.hhs.gov; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

I think social can be first thing in a normal business day. The goal is to get this to reporters/producers for morning broadcasts. I think we're more likely to hit them with PRNewswire rather than Twitter. Correct me if I'm wrong.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Date: August 26, 2020 at 12:33:34 PM EDT

To: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>, Miller, Emily <Emily.Miller@fda.hhs.gov>, Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

Including social? Asking because my piece is a manual operation... unlike web.

Brad Kimberly

Director, Social Media

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Tel: 240-402-1002 | Cell: brad.kimberly@fda.hhs.gov











From: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:32 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

Update: I just spoke to Jeremy and he's going to put the pieces in motion for a 4 am distribution tomorrow.

Shannon P. Hatch

Media Relations Director

Office of Media Affairs Office of External Affairs Mobile: (b) (6)

From: Miller, Emily < Emily. Miller @fda.hhs.gov> Sent: Wednesday, August 26, 2020 12:25 PM

To: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >; Kimberly, Brad < Brad. Kimberly@fda.hhs.gov >; Hatch,

Shannon <Shannon.Hatch@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

That's cool – the headline will get their attention but Brad is right that we need to make that link.

-EM

Call/text (b) (6)

From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:24 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

This is what we've said in quotes in the past: Practicing good hand hygiene, which includes using alcohol-based hand sanitizer if soap and water are not readily available, is an important public health tool for all Americans to employ.

From: Miller, Emily < Emily. Miller@fda.hhs.gov> Sent: Wednesday, August 26, 2020 12:22 PM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>; Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

-EM

Call/text (b) (6)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:21 PM

To: Hatch, Shannon <<u>Shannon.Hatch@fda.hhs.gov</u>>; Miller, Emily <<u>Emily.Miller@fda.hhs.gov</u>>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: RE: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

I just wanted to let you guys know that I asked Jeremy why this was flagged as a COVID update in the headline when it doesn't even mention the pandemic in the story. Because it came through my team on the JIC process.

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: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:17 PM To: Miller, Emily < Emily. Miller @fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >; Kimberly, Brad < Brad. Kimberly@fda.hhs.gov >;

Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Subject: Emily -- FOR YOUR REVIEW -- Hand Sanitizer Press Release

Importance: High

Hi Emily,

Here's the near-final hand sanitizer press release. Press officer is proofing now.

I know you want this to go out at 4 am tomorrow, but I think the risk for unanticipated logistical issues is too great. I recommend we follow the typical SOP and issue the press release this afternoon.

I agree with your goals/rationale behind the early-morning release schedule. I want to work with the team to explore options of how we achieve that goal. At the same time, I don't want to introduce process changes that put us at risk of putting out incorrect information. The SOP protects us from making version control issues and it also ensures we follow HHS ASPA's clearance protocols.

Thanks, Shannon

P.S. I see that our e-mails are crossing. Clicking "send" on this and will read your other e-mails.

Shannon P. Hatch

Media Relations Director

Office of Media Affairs Office of External Affairs Mobile: (b) (6)

From: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov> Sent: Wednesday, August 26, 2020 12:04 PM

To: OC OEA OMA-Press < OCOEAOMA-Press@fda.hhs.gov>

Subject: proof ASAP?

Thank you!

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 4:11:51 PM

To: Caccomo, 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]

Subject: FW: Qs from Sanjay Gupta's team

FYI I'm going to send just the new quote to the sanjay team.

From: Miller, Emily

Sent: Monday, August 24, 2020 3:41 PM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>; Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>; Shah,

Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Qs from Sanjay Gupta's team



From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Monday, August 24, 2020 2:06 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >; Miller, Emily < Emily. Miller@fda.hhs.gov >; Felberbaum,

Michael < Michael. Felberbaum@fda.hhs.gov > Subject: RE: Qs from Sanjay Gupta's team

agreed

John 'Wolf' Wagner Associate Commissioner

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Monday, August 24, 2020 2:05 PM

To: Miller, Emily < Emily. Miller @fda.hhs.gov>; Felberbaum, Michael < Michael. Felberbaum @fda.hhs.gov>; Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>
Subject: Qs from Sanjay Gupta's team

Sanjay's producers sent over blow:

May we be able to speak with the point person who made the decision in CBER? Whether that is Dr. Peter Marks, or someone else?

In addition, while I understand that Dr. Hahn did not make the review decision, was he involved in the decision process at all? If so, what role did he play?

And even if he wasn't involved in the decision making, did he review any of the data?

(b)(5)

I already told them that CBER made decision, not Dr. Hahn. (b) (5)

OK?

Stephanie Caccomo

Media Relations Director

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Desk: 301.348.1956

Cell: (b)

stephanie.caccomo@fda.hhs.gov

From: Kounang, Nadia < Nadia. Kounang@turner.com >

Sent: Monday, August 24, 2020 1:59 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Cc: Sealy, Amanda < Amanda. Sealy@cnn.com > Subject: Re: Sanjay--FDA EUA decision memo

Thanks for the speedy response. Understood that CBER made the decision.

May we be able to speak with the point person who made the decision in CBER? Whether that is Dr. Peter Marks, or someone else?

In addition, while I understand that Dr. Hahn did not make the review decision, was he involved in the decision process at all? If so, what role did he play?

And even if he wasn't involved in the decision making, did he review any of the data?

And just to make sure – because I didn't see it embedded within the links that you sent – and I may have just overlooked it – but wanted to confirm that this is the EUA that was presented to the FDA:

https://www.fda.gov/media/141481/download

Thanks. Nadia

From: "Caccomo, Stephanie" < Stephanie. Caccomo@fda.hhs.gov>

Date: Monday, August 24, 2020 at 1:42 PM

To: Nadia Kounang < Nadia. Kounang@turner.com > Cc: Amanda Sealy < Amanda. Sealy@cnn.com> Subject: RE: Sanjay--FDA EUA decision memo

Dr. Hahn did not make this review decision, to be clear, our Center for Biologics Evaluation and Research made this decision.

The information we can share is outlined in the request from ASPR and our decision memo.

Stephanie Caccomo

Media Relations Director

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Desk: 301.348.1956

stephanie.caccomo@fda.hhs.gov

From: Kounang, Nadia < Nadia. Kounang@turner.com >

Sent: Monday, August 24, 2020 1:41 PM

To: Caccomo, Stephanie < Stephanie < Stephanie.Caccomo@fda.hhs.gov>

Cc: Sealy, Amanda < <u>Amanda.Sealy@cnn.com</u>> Subject: Re: Sanjay--FDA EUA decision memo

Hi Stephanie -

Hoping you might be able to help us answer this question:

In the FDA's decision making process on yesterday's EUA for convalescent plasma — do you know if the FDA reviewed any additional data beyond what was submitted in the EUA application? If so, what data was that and can that be made available to us? Also, if there was additional information reviewed in the decision making process, do you know if that is information that was also made available to Dr. Hahn and if he reviewed that information?

Much thanks for your help with this.

Best, Nadia Kounang CNN Health

From: Amanda Sealy < Amanda. Sealy@cnn.com >

Date: Sunday, August 23, 2020 at 6:40 PM

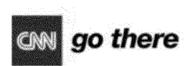
To: "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>, "Gupta, Sanjay" <scalpel@turner.com>

Cc: Nadia Kounang < Nadia.Kounang@turner.com > Subject: Re: Sanjay--FDA EUA decision memo

Thank you for this

Amanda Sealy | Senior Producer Mobile: +(b) (6)

Desk: +1 404-827-3556



From: Stepanie Caccomo <Stephanie.Caccomo@fda.hhs.gov>

Date: Sunday, August 23, 2020 at 6:38 PM **To:** "Gupta, Sanjay" < scalpel@turner.com>

Cc: "amanda.sealy@cnn.com" < Amanda.Sealy@cnn.com>

Subject: Sanjay--FDA EUA decision memo

Sanjay-

Wanted to make sure you had our press release, which links to our decision memo that outlines the data used to make the decision.

https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescentplasma-potential-promising-covid-19-treatment https://www.fda.gov/media/141480/download

Stephanie Caccomo Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 1:00:03 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: RE: Media Call



-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, August 27, 2020 12:57 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Media Call

When is the media call on Abbott today?

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 10:53:37 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: FW: swan coverage

I'm waiting until after cbs to give SH anything to distract him, but per your suggestion, I put together this list on the Swan HBO plan. Once I get SH to understand what hes' walking into, I'll play bad cop with swan so he can still get good coverage

-EM

Call/text (b) (6)

From: Emily Miller (b) (6)

Sent: Monday, August 24, 2020 10:33 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: swan coverage

Axios's Jonathan Swan is the latest interviewer to leave Trump grasping on TV Jonathan Swan reveals the simple secret to exposing Trump's lies: basic follow-up questions

Jonathan Swan's Face Is the 2020 Meme We Needed -- During his viral Trump interview, the Axios reporter's pained expressions said it all.

Trump's Axios interview was a disaster.

Journalist's gobsmacked reactions during Trump interview are Twitter's too

Social media reacts to Trump's 'shocking' Axios interview with Jonathan Swan on HBO

Trump Collapses Under Pressure of Extremely Basic Follow-Up Questions About COVID-19

Fact-checking 22 claims from President Trump's Axios interview with Jonathan Swan

Psychiatrist as Fly-On-The-Wall at Trump's Axios Interview

The Axios Interview Showed Us an Important Threshold for the President

Emily Miller

Call/Text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 4:36:52 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, 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]

CC: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

Subject: RE: Response to 35% reporters ASAP

Wolf told me to send it out. I don't know.

From: Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>

Sent: Monday, August 24, 2020 4:36 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >; Miller, Emily < Emily. Miller@fda.hhs.gov >; Felberbaum,

Michael < Michael. Felberbaum@fda.hhs.gov>
Cc: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Subject: RE: Response to 35% reporters ASAP

Did WH clear?

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Date: August 24, 2020 at 4:18:04 PM EDT

To: Miller, Emily < Emily.Miller@fda.hhs.gov>, Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov>, Wagner, John < John.Wolf.Wagner@fda.hhs.gov>

Subject: RE: Response to 35% reporters ASAP

We'll get out to reporters. Emily do you want to tweet it?

Stephanie Caccomo

Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301 348 1956

Desk: 301.348.1956 Cell: (b) (6)

stephanie.caccomo@fda.hhs.gov

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Sent: Monday, August 24, 2020 4:07 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >; Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >

Cc: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Wagner, John < John.Wolf.Wagner@fda.hhs.gov>

Subject: Response to 35% reporters ASAP

Michael and Stephanie,

This is cleared and so please have our team send to every reporter who has asked about it since the presser last night:

Email body:

Below is an on the record quote below is from Dr. Peter Marks, Director of the FDA Center for Biological Evaluation and Research:

"FDA reviewed data from multiple sources, including over a dozen published studies, as well as the prepublication data from the Mayo Clinic. We also conducted our own analysis of the data from the national Expanded Access Program for COVID-19 convalescent plasma. Note that in the Expanded Access Program, the antibody titer of the plasma given to patients was not known until after patients were treated, potentially reducing any bias. Although the effect size with the administration of COVID-19 convalescent plasma varies somewhat from study to study, likely in part to the different populations treated, the FDA notes that there appears to be roughly a 35 percent relative improvement in the survival rates of patients who were treated with higher titer plasma when compared to those treated with lower titer plasma. Given the safety profile observed, the totality of evidence regarding potential efficacy more than adequately met the 'may be effective' standard for granting an Emergency Use Authorization."

Let me know if you get any responses that need more info.

Thanks, Emily

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 9:27:29 AM

To: 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]

Subject: RE: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Definitely needed as part of the overall strategy. Let's add to the working doc.

-EM

Call/text (b) (6)

From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 9:15 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Oh, one more thing. We should create a COVID Vaccine Development landing page on the web where all these materials can live, including adding previous resources/links to op-eds, interviews, etc.

From: Felberbaum, Michael

Sent: Tuesday, August 25, 2020 9:10 AM

To: Miller, Emily < Emily.Miller@fda.hhs.gov >; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >

Subject: Action item due Thursday 8/27 from OEA Leadership Check-in: Vaccine Strategy

Hi both,

On the OEA leadership check-in today, Wolf asked that each OEA office provide by Thursday to Jason Strachman-Miller some ideas for making an eventual rollout of a COVID vaccine successful (based in part on some lessons learned from the plasma rollout).

Emily, I believe you said you were working on some sort of strategic comms plan on this, so you may want to let Wolf know that's in the works. I also know that ASPA is working on a full-on public education campaign.

I'm sharing a few notes, but since I'll be out, would one of you be able to close the loop on this Thursday ask?





Thanks,

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/28/2020 8:59:29 AM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Kimberly, Brad

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

Subject: RE: Daily management call

Comm needs me now in WO. Stay tuned. Gotta drive.

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Friday, August 28, 2020 8:46 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly, Brad

<Brad.Kimberly@fda.hhs.gov>
Subject: RE: Daily management call

Sounds good. What time would be good for you today to have a "huddle" by phone with the four of us (Brad, Stephanie, you, me)?

Shannon P. Hatch

Media Relations Director

Office of Media Affairs
Office of External Affairs
Mobile: (b) (6)

From: Miller, Emily < Emily. Miller @fda.hhs.gov>

Sent: Friday, August 28, 2020 8:44 AM

To: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly,

Brad < Brad. Kimberly@fda.hhs.gov > Subject: RE: Daily management call

Oh I didn't mean today, I meant going forward when we choose the best time around commissioner call.

Also I cancelled the 11am because I'm at white oak with commissioner. Can we all talk today and then we get together with them when I can communicate to them how much things have changed and we're trying to sort out our new responsibilities?

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Friday, August 28, 2020 5:35 AM

To: Miller, Emily < Emily. Miller@fda.hhs.gov>; Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>; Kimberly, Brad

<<u>Brad.Kimberly@fda.hhs.gov</u>> **Subject:** Re: Daily management call

I can make either of those times work for a daily call.

Today I have a lot of extra calls on my calendar but will shuffle to prioritize a daily management call.

From: Miller, Emily < Emily.Miller@fda.hhs.gov Date: August 27, 2020 at 11:09:21 PM EDT

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov >, Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >, Kimberly,

Brad <<u>Brad.Kimberly@fda.hhs.gov</u>> **Subject:** Daily management call

What about 845-9 or 915-930 to get our ducks in the row for the day?

Emily Miller
FDA Assistant Commissioner for Media Affairs
Call/text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 4:01:31 PM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP



-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:59 PM

To: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Miller, Emily < Emily.Miller@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP



John 'Wolf' Wagner Associate Commissioner

From: Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:57 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP

Agree that HHS and WH should be made aware. Not sure they would recommend responding especially after the hit piece on Hahn again this am.

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:51 PM

To: Wagner, John < John.Wolf.Wagner@fda.hhs.gov >; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov >

Cc: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>

Subject: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP

Wolf and Keagan, We need to at least send this to Caputo and WH to see if they want to chime in here? I'm not concerned for my reputation but for Dr. Hahn appear to being "handled" by WH and conservative right wing nut (me) so maybe we can tramp down that narrative?

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Sent: Tuesday, August 25, 2020 3:46 PM **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Subject: FW: Wolf/Emily: STAT story on FDA, deadline ASAP

Stephanie Caccomo

Media Relations Director

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: Wagner, John < John. Wolf. Wagner@fda.hhs.gov >

Sent: Tuesday, August 25, 2020 3:41 PM

To: Caccomo, Stephanie < Stephanie < Stephanie < Stephanie < Stephanie.Caccomo@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov >; Hatch, Shannon < Shannon.Hatch@fda.hhs.gov >

Subject: RE: Wolf/Emily: STAT story on FDA, deadline ASAP

You think? 😊

Wow....

John 'Wolf' Wagner

Associate Commissioner

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Sent: Tuesday, August 25, 2020 3:41 PM

To: Wagner, John < John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily < Emily.Miller@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: Wolf/Emily: STAT story on FDA, deadline ASAP

Hi-

Do you want us to decline to comment?

Stephanie Caccomo

Media Relations Director

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: Lev Facher < lev.facher@statnews.com Sent: Tuesday, August 25, 2020 3:05 PM

To: FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum,

Michael < Michael.Felberbaum@fda.hhs.gov >; Wagner, John < John.Wolf.Wagner@fda.hhs.gov >

Cc: Nicholas Florko < <u>nicholas.florko@statnews.com</u>> Subject: Re: STAT story on FDA, deadline ASAP All:

We're running another piece tomorrow on several administration moves perceived as undercutting the FDA, which include:

- -Concern within FDA's own ranks, citing three senior FDA officials, about Emily Miller's role and past writings on gun rights, transgender health issues, and Obamacare ads on birth control (one headlne in a Washington Times column:
- "New Obamacare ads make young women look like sluts," many others)
- -The president's "deep state" tweet
- -The appointment of David Gortler, who advocated for a mass firing FDA in a STAT op-ed a few years ago
- -The political tint to Sunday's briefing re: the plasma EUA

We'd like to request an **interview with Dr. Hahn** regarding the last several days' events, personnel shifts at FDA, flagging morale within the agency, and our forthcoming story's reporting that senior FDA officials believe Dr. Hahn should be doing more to combat the White House's actions that, intentionally or not, have damaged the agency's reputation and undercut its authority.

Please feel free to reach out anytime this evening to respond to any of the themes above or discuss scheduling an interview with the commissioner.

Lev

On Tue, Aug 25, 2020 at 11:09 AM FDA Office of Media Affairs <FDAOMA@fda.hhs.gov> wrote:

Good Morning,

Please reference the below link for the most recent information on this subject. We'll be sure to flag any additional information for you when it is available.

 $\frac{https://www.cbsnews.com/video/fda-commissioner-hahn-responds-to-criticism-about-politicization-of-covid-19-treatment-authorization/\#x$

Thank you.

From: Lev Facher < lev.facher@statnews.com Sent: Monday, August 24, 2020 4:30 PM

To: FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Nicholas Florko <nicholas.florko@statnews.com>

Subject: STAT story on FDA, deadline ASAP

All: Lev with STAT here. My colleague Nick Florko and I are running a story tomorrow that raises questions about Commissioner Hahn's ability to resist political pressure at FDA and steer the agency through uncertain times amid Covid. It makes a number of points below, on which we'd love FDA's response if possible. Thanks in advance for your help: I'm available at (510)-374-8880.

-Commissioner Hahn has no experience in government, and has just a small circle of FDA advisors on whom he relies heavily: Anand Shah, Jeet Guram, Colin Rom, and Lowell Zeta. Collectively, these folks have minimal experience in FDA leadership.

- -Commissioner Hahn's claim last night that of "100 people who are sick with Covid-19 35 would have been saved" makes two hugely significant errors which the FDA has not recanted: The source of the 35% mortality reduction statistic, itself is unclear to many outside experts, and even if it's correct, it of course doesn't "save" 35% percent of all Covid patients; it reduces the mortality by 35%.
- -Unlike past commissioners, Dr. Hahn does not have significant relationships with the former commissioners (though we quote an outside voice explaining that he is a) a political outsider and b) has mostly run the agency during a pandemic, i.e., this is to be expected.)
- -Emily, your role is typically not one filled by a political appointee.
- -The story doesn't include voices questioning the science underpinning the plasma EUA -- only the presentation of the decision, which people viewed as highly politicized.

__

Lev Facher Washington Correspondent

Cell/Signal/WhatsApp: (510) 374-8880

@levfacher

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@statnews | statnews.com | facebook.com/statnews

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Lev Facher Washington Correspondent Cell/Signal/WhatsApp: (510) 374-8880

@levfacher

STAT | Reporting from the frontiers of health and medicine

@statnews | statnews.com | facebook.com/statnews

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 12:16:35 PM

To: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]; Kahn, Jeremy

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]; OC OEA OMA-Press

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]

Subject: RE: proof ASAP?

I got this from Shannon too and she knows the time to release it so please coordinate.

-EM

Call/text (b) (6)

From: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:07 PM

To: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>; OC OEA OMA-Press < OCOEAOMA-Press@fda.hhs.gov>

Subject: RE: proof ASAP?

I can!

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov> Sent: Wednesday, August 26, 2020 12:04 PM

To: OC OEA OMA-Press < OCOEAOMA-Press@fda.hhs.gov>

Subject: proof ASAP?

Thank you!

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 4:38:30 PM

To: Michael Carter [mcarter@newsmax.com]

Subject: RE: Chris Salcedo Show Interview - Newsmax TV

I'm sorry but we have to pass. The White House does not want us on national TV but on Texas only.

-EM

Call/text (b) (6)

From: Michael Carter <mcarter@newsmax.com>

Sent: Tuesday, August 25, 2020 4:20 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: RE: Chris Salcedo Show Interview - Newsmax TV

Hi Emily,

His appearance on Newsmax TV will be re-aired on his radio program the following day...so it will essentially be twice the media opp for one interview!

Think we can make this work this week?

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 4:13 PM
To: Michael Carter <mcarter@newsmax.com>

Subject: RE: Chris Salcedo Show Interview - Newsmax TV

Hey there, Nice to meet you. I offered Commissioner Hahn to Chris just for radio in Texas. The White House asked us to do media in Dallas this week and so that's why we reached out to him. If he wants to take a pass on radio, we can try to fit in the TV show one day in the future. Thanks!

-EM

Call/text (b) (6)

From: Michael Carter < mcarter@newsmax.com>

Sent: Tuesday, August 25, 2020 3:55 PM **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Subject: Chris Salcedo Show Interview - Newsmax TV

Hi Emily,

Reaching out to see Commissioner Hahn can join us on Thursday or Friday this week on the *Chris Salcedo Show* on Newsmax TV.

Our show airs LIVE from 5-6pm ET, so would love to find some time then. But we can also conduct a pre-taped interview between 1pm-4pm ET on Thursday or Friday as well.

Thank you!

Michael

Michael Carter Booking Producer The Chris Salcedo Show

Newsmaxty

805 Third Avenue, 22nd Floor New York, NY 10022

Cell: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 10:13:52 AM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: FW: DRAFT clearance for press releases

Do not forward this email. It's just for you to understand what's happening. Maybe it makes sense to move the team call to later today or tomorrow so they don't get more confusing info?

-EM

Call/text (b) (6)

From: Miller, Emily

Sent: Wednesday, August 26, 2020 10:13 AM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Subject: DRAFT clearance for press releases

Wolf,

We really need to nail down the clearance process for media today because we have so many things on hold right now that my team said are important to release.



Emily Miller

FDA Assistant Commissioner for Media Affairs

Call/text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 3:59:44 PM

To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

RE: HEAD SHOT ... Availability Subject:

I would never have thought of that! Maybe I'll get there early and do my makeup there... Thanks for thinking like a producer!

-FM

Call/text (b) (6)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:57 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wolf, Ailis * <Ailis.Wolf@fda.hhs.gov>

Cc: Saghafi, Michelle < Michelle. Saghafi@fda.hhs.gov>

Subject: RE: HEAD SHOT... Availability

I'll let Ailis address the other questions. But one thing we have never had to consider before... masks.

Be sure to bring makeup with you to touch up once your mask comes off for the shoot.

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) brad.kimberly@fda.hhs.gov













From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:55 PM To: Wolf, Ailis * <Ailis.Wolf@fda.hhs.gov>

Cc: Saghafi, Michelle <Michelle.Saghafi@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Subject: RE: HEAD SHOT... Availability

Also are you the photographer? If so, can I get guidelines on color to wear and what will be the backdrop so I can not wear same color. And in the interest of total vanity, do you do any fixing of the picture afterwards for my lines and stuff? Thanks!

-EM

Call/text (b) (6)

From: Wolf, Ailis * <Ailis.Wolf@fda.hhs.gov> Sent: Tuesday, August 25, 2020 3:35 PM

To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Saghafi, Michelle <Michelle.Saghafi@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Subject: RE: HEAD SHOT... Availability

Hi Emily -

It's nice to meet you virtually. I look forward to working with you.

Would 10 am, 10:30 am or 11 a.m. on Thursday, September 3 work for you?

Thanks, Ailis

Ailis Wolf

Project Manager (Contractor)

Office of External Affairs U.S. Food and Drug Administration

Office: 240-402-4685 Mobile: (b) (6) Ailis.Wolf@fda.hhs.gov











From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 2:20 PM To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Cc: Saghafi, Michelle <Michelle.Saghafi@fda.hhs.gov>; Wolf, Ailis * <Ailis.Wolf@fda.hhs.gov>

Subject: RE: HEAD SHOT ... Availability

Ailis, come up with some availability for Cade, and let's see if we can sync this up.

Also? Probably not a bad idea for Wolf to do this, too, since we'll have the photographer in house.

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: Miller, Emily < Emily. Miller @fda.hhs.gov>

Sent: Tuesday, August 25, 2020 2:19 PM

To: Kimberly, Brad < Brad.Kimberly@fda.hhs.gov>

Cc: Saghafi, Michelle <Michelle.Saghafi@fda.hhs.gov>; Wolf, Ailis * <Ailis.Wolf@fda.hhs.gov>

Subject: RE: HEAD SHOT... Availability

Can we do one day next week so I can work out of there while I do it?

Not early morning because I'm a girl and have to do my own hair and makeup which is an extensive process at my age for a headshot ©

-EM

Call/text (b) (6)

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 1:56 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Saghafi, Michelle < Michelle.Saghafi@fda.hhs.gov >; Wolf, Ailis * < Ailis.Wolf@fda.hhs.gov >

Subject: HEAD SHOT... Availability

Good afternoon...

Ailis Wolf is our project manager on the Brillient contract, and she's working to coordinate a photographer for your official FDA headshot.

Do you have a date and time that you would prefer for us to set this shoot?

It would occur in the Courtroom Studio (in Bldg 1) at White Oak and should only take 30 minutes tops.

Thanks!

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 11:06:26 AM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: RE: QUERY — SALON

Both Caputo and Buckham told me before I started that he will handle the expected media attacks on me. Is that no longer the case?

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 10:41 AM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: RE: QUERY — SALON

I saw this this morning. Not using any FDA/USG sites, you're welcome to address them directly if you wish. That's the best way.

John 'Wolf' Wagner Associate Commissioner

From: Miller, Emily < Emilto:Emily < Emilto:Emily < Emily <a href="mailto:Emily Emily <a h

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Subject: RE: QUERY — SALON

Wolf -- The story came out and it's full of inaccuracies. Can someone at HHS ASPA or WH at least on background ask for correction on the facts so this doesn't become the permanent narrative that I was put in just now and undercut the credibility of FDA and Dr. Hahn?

https://www.salon.com/2020/08/26/former-one-america-news-correspondent-emily-miller-gets-senior-fda-post/

If you want, I can list out the specific false info, but top is

1) I was called by White House in May to take this job while I was running a Texas county government coronavirus task force and spokesman for it 2) I started talking to Hahn in June 3) My approval was July 4) My start date was Aug 17th 5) I worked for OAN in 2016 and interviewed Trump many times but have not talked to the president since I last interviewed him a week before the election. 6) I've never met Caputo until I walked in the first day and he got me through the security desk.

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 7:27 AM

To: Miller, Emily < Emily. Miller@fda.hhs.gov >; Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov >

Subject: RE: QUERY — SALON

Let it be. Will only get weirder.

John 'Wolf' Wagner Associate Commissioner

From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 8:44 PM

To: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Subject: Fwd: QUERY — SALON

The left finally figured out I'm at FDA. See questions below. I actually don't mind having Stephanie answer some questions to take away the sinister narrative.

But I don't want to make decisions on my own press because doctors don't operate on themselves.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Roger Sollenberger <rsollenberger@salon.com>

Date: August 25, 2020 at 6:01:24 PM EDT **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: QUERY — SALON

Hi Emily, and hope you're well!

Wondering if you could answer a few questions about your hire.

Did someone from the administration reach out to you about this position?

Did you speak with Michael Caputo ahead of your hiring?

How do you reconcile your time at a pro-Trump news outlet with your public service employment?

When were you hired? Who was former Acting Asst Commissioner, and where are they now?

Thanks!

Roger Sollenberger Staff Writer, News

(b) (6) (Cell, WhatsApp, Signal)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 10:25:59 PM

To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

Subject: Declined: Michael 000

Location: Cabin in the Woods (the non-murderous type)

Start: 8/26/2020 8:00:00 PM **End**: 8/31/2020 8:00:00 PM

Show Time As: Free

Recurrence: (none)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 10:41:15 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: Accepted: Dr. Hahn media/scheduling

Location: SC to call EM

Start: 8/25/2020 11:00:00 AM **End**: 8/25/2020 11:30:00 AM

Show Time As: Busy

Recurrence: (none)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/28/2020 8:56:52 AM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

Subject: Accepted: Comms Daily Check-In

Location: 1-877-465-7975, (b) (6)

Start: 8/28/2020 4:45:00 PM **End**: 8/28/2020 5:00:00 PM

Show Time As: Busy

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE August 26, 2020

COVID-19 Update: FDA Warns Consumers about Hand Sanitizer Packaged in Food and Drink Containers

Silver Spring, MD --- The U.S. Food and Drug Administration (FDA) is warning consumers about [HYPERLINK "https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19"] that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. The agency has discovered that some hand sanitizers are being packaged in beer cans, children's food pouches, water bottles, juice bottles and vodka bottles. Additionally, the FDA has found hand sanitizers that contain food flavors, such as chocolate or raspberry.

"I am increasingly concerned about hand sanitizer being packaged to appear to be consumable products, such as baby food or beverages. These products could confuse consumers into accidentally ingesting a potentially deadly product. It's dangerous to add scents with food flavors to hand sanitizers which children could think smells like food, eat and get alcohol poisoning," said FDA Commissioner Stephen M. Hahn, M.D. "Manufacturers should be vigilant about packaging and marketing their hand sanitizers in food or drink packages in an effort to mitigate any potential inadvertent use by consumers. The FDA continues to monitor these products and we'll take appropriate actions as needed to protect the health of Americans."

In one recent example of consumer confusion, the FDA received a report that a consumer purchased a bottle they thought to be drinking water but was in fact hand sanitizer. The agency also received a report from a retailer about a hand sanitizer product marketed with cartoons for children that was in a pouch that resembles a snack. Drinking only a small amount of hand sanitizer is potentially lethal to a young child, who may be attracted by a pleasant smell or brightly colored bottle of hand sanitizer.

Hand sanitizer can be toxic when ingested. The FDA continues to see an increasing number of adverse events with hand sanitizer ingestion, including cardiac effects, effects on the central nervous system, hospitalizations and death, primarily reported to poison control centers and state departments of health. For more information, consumers should refer to the FDA's guidelines on [HYPERLINK "https://www.fda.gov/consumers/consumer-updates/safely-using-hand-sanitizer"] as well as [HYPERLINK "https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19"].

The FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's [HYPERLINK "https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program" \o "MedWatch: The FDA Safety Information and Adverse Event Reporting Program"] program (please provide the agency with as much information to identify the product as possible).

The FDA continues to proactively work with manufacturers to recall potentially dangerous hand sanitizer products and is strongly encouraging retailers to remove these products from store shelves and online marketplaces. A [HYPERLINK "https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol" \I "products"] of hand sanitizer products the FDA urges consumers not to use, along with a description for consumers on how to use the list, has been posted to the agency's website, which is being updated regularly.

###

Consumer Inquiries: [HYPERLINK "mailto:covid-19-hand-sanitizers@fda.hhs.gov"] or 888-INFO-FDA

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 12:12:52 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]

Subject: FW: proof ASAP?

Attachments: FDA Press Release- Sanitizers Packaging -FINAL.docx

Can we keep this going in same line of clearance etc?

-EM

Call/text (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov> Sent: Wednesday, August 26, 2020 12:04 PM

To: OC OEA OMA-Press <OCOEAOMA-Press@fda.hhs.gov>

Subject: proof ASAP?

Thank you!

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 11:05:01 AM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

Subject: Accepted: In-Person (@ WO) Touch Base: Rom/Miller/Wagner/Shah/Lenihan/Hahn

Location: Commissioner's Suite (WO1/2217)

Start: 8/27/2020 12:00:00 PM **End**: 8/27/2020 12:30:00 PM

Show Time As: Busy

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 9:12:46 AM

To: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]

Subject: RE: 2nd Attempt: Meeting Request: [In-Person] Discussion: Comms Strategy

I don't understand what I need to do here?

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (5)

From: Zembower, Jenna < Jenna. Zembower@fda.hhs.gov>

Date: August 25, 2020 at 8:56:43 AM EDT

To: Olivarria, Frank Frank.Olivarria@fda.hhs.gov, Strachman-Miller, Jason Jason.Strachman-Miller, Jason.Strachman-

Miller@fda.hhs.gov>, Flowers, Susan <Susan.Flowers@fda.hhs.gov>, Miller, Emily

<Emily.Miller@fda.hhs.gov>

Subject: RE: 2nd Attempt: Meeting Request: [In-Person] Discussion: Comms Strategy

Good to go on this call – whatever works for everyone else. Thanks!

From: Olivarria, Frank < Frank. Olivarria@fda.hhs.gov>

Sent: Monday, August 24, 2020 11:19 PM

To: Strachman-Miller, Jason <Jason.Strachman-Miller@fda.hhs.gov>; Flowers, Susan <Susan.Flowers@fda.hhs.gov>;

Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: 2nd Attempt: Meeting Request: [In-Person] Discussion: Comms Strategy

Good evening, attempting this scheduling again – as a reminder, it is for in-person at HHS.

In-Person Discussion: Comms Strategy (Meeting to occur at HHS/FDA Suite)	Thursday, 8/27: 9:15- 9:45 AM	Thursday, 8/27: 9:45- 10:15 AM	Thursday, 8/27: 10:00- 10:30 AM	Friday, 8/28: 11:00-11:30 AM	Friday, 8/28: 12:30-1:00 PM	Friday, 8/28: 4:30-5:00 PM
Keagan Lenihan (Susan)						
Anand Shah (Jenna)	Available	Available	Available	Available	Available	Available
Wolf Wagner (Jason)						
Emily Miller						

Thank you, Frank

From: Olivarria, Frank

Sent: Friday, August 21, 2020 4:50 PM

To: Strachman-Miller, Jason < Jason. Strachman-Miller@fda.hhs.gov>; Flowers, Susan < Susan. Flowers@fda.hhs.gov>;

Zembower, Jenna <<u>Jenna.Zembower@fda.hhs.gov</u>>; Emily Miller <<u>miller@engagemedias.com</u>>

Subject: RE: Meeting Request: [In-Person] Discussion: Comms Strategy

Hi all,

Please hold off on further responses. We are going to look at Friday options instead. TY!

From: Strachman-Miller, Jason < Jason.Strachman-Miller@fda.hhs.gov>

Sent: Friday, August 21, 2020 4:29 PM

To: Olivarria, Frank < Frank. Olivarria@fda.hhs.gov >; Flowers, Susan < Susan. Flowers@fda.hhs.gov >; Zembower, Jenna

<Jenna.Zembower@fda.hhs.gov>; Emily Miller <miller@engagemedias.com>

Subject: RE: Meeting Request: [In-Person] Discussion: Comms Strategy

Greetings all,

Below is Wolf's availability. Have a nice weekend!

Cheers.

In-Person Discussion: Comms Strategy (Meeting to occur at HHS/FDA Suite)	Thursday, 8/27: 9:15- 9:45 AM	Thursday, 8/27: 9:45- 10:15 AM	Thursday, 8/27: 10:00- 10:30 AM
Keagan Lenihan (Susan)			
Anand Shah (Jenna)			
Wolf Wagner (Jason)	Available	Available	Available, not preferred
Emily Miller			

Frank

Frank A. Olivarria

Management and Program Analyst Immediate Office, Office of the Commissioner U.S. Food and Drug Administration

Tel: 240-402-9882











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/28/2020 8:54:49 AM

To: Perrone, Matthew [MPerrone@ap.org]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: AP Questions-Dr. Hahn Story

I'll let him know.

-EM

Call/text (b) (6)

From: Perrone, Matthew < MPerrone@ap.org>

Sent: Friday, August 28, 2020 8:46 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: AP Questions-Dr. Hahn Story

And my cell phone is (b) (6)

But the 9863 line also forwards to my cell.

From: Miller, Emily < Emily. Miller@fda.hhs.gov>

Sent: Friday, August 28, 2020 8:42 AM

To: Perrone, Matthew < MPerrone@ap.org>; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: AP Questions-Dr. Hahn Story

[EXTERNAL]

On the issue of commissioner trying to call you and texting you, he showed me the text and number and he has (b) (6) Is this not correct?

-EM

Call/text (b) (6)

From: Perrone, Matthew < MPerrone@ap.org > Sent: Thursday, August 27, 2020 7:43 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: AP Questions-Dr. Hahn Story

Thanks much

From: Miller, Emily < Emily.Miller@fda.hhs.gov Sent: Thursday, August 27, 2020 7:07 PM

To: Perrone, Matthew <MPerrone@ap.org>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: AP Questions-Dr. Hahn Story

[EXTERNAL]

Doing my best to get answers.

Will give SH this number so he has the right one.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Perrone, Matthew < MPerrone@ap.org > Date: August 27, 2020 at 6:45:21 PM EDT

To: Miller, Emily <Emily.Miller@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: AP Questions-Dr. Hahn Story

Hi Emily,

Thanks so much for letting me know.

I can assure you I haven't received any calls or texts from Dr. Hahn this week (or ever, in fact). Perhaps he's confusing me with another reporter, or perhaps he doesn't have my correct number. Both of these forward to me: (202) 641-9863 and (b) (6)

I understand the timing issue. No problem. I was just hoping to confirm some of the great information I learned today, but we probably don't need that level of detail.

Below is the most important issue and one I raised in my initial email to Stephanie on Tuesday. Any response from FDA or Dr. Hahn would be appreciated:

1. Many former FDA officials have told the AP that Dr. Hahn's misstatement on the effectiveness of plasma has damaged the FDA's reputation at a critical time. Do you agree or disagree? Does Dr. Hahn have any plans or ideas to repair FDA's public image in the weeks and months ahead? If so, can you give us some examples of what we should expect to see?

Thanks,

Matthew Perrone AP Health Writer (202) 641-9863 mperrone@ap.org @AP FDAwriter

The Associated Press, founded in 1846, is the essential global news network, delivering fast, unbiased news from every corner of the world to all media platforms and formats. With a network of 240 bureaus, AP is the largest and most trusted source of independent news and information, providing content to more than 15,000 news outlets. On any given day, more than half the world's population sees news from AP.

From: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Thursday, August 27, 2020 6:23 PM

To: Caccomo, Stephanie < Stephanie Stephanie Stephanie Stephanie.caccomo@fda.hhs.gov; Perrone, Matthew MPerrone@ap.org>

Subject: RE: AP Questions-Dr. Hahn Story

[EXTERNAL]

Matthew,

Dr. Hahn just told me he called you multiple times earlier this week and texted you and you never responded.

It's wayyyy too late in the day for these questions to be considered and cleared for a story tomorrow, and you know that. I don't remember asking you to put questions in writing.

If you want something on background, we can provide but we can't pull together answers and get clearance this late.

Emily

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >

Sent: Thursday, August 27, 2020 4:29 PM
To: Perrone, Matthew < MPerrone@ap.org>
Cc: Miller, Emily < Emily.Miller@fda.hhs.gov>
Subject: RE: AP Questions-Dr. Hahn Story

Received

Stephanie Caccomo

Media Relations Director

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: Perrone, Matthew < MPerrone@ap.org > Sent: Thursday, August 27, 2020 4:27 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Subject: AP Questions-Dr. Hahn Story

Importance: High

Hi Stephanie,

Thanks for all your help today. Had a nice long chat with Emily. She asked me to put any questions in writing, so please see the list below. We still hope we can talk to Dr. Hahn soon for inclusion in our story.

- 1.) When did FDA staff decide that convalescent plasma met the standard for an EUA and should be authorized?
- 2.) Why did the FDA decide to make the EUA announcement on Sunday afternoon? Did agency staff worry about the conspicuous timing of making a major COVID-19 announcement the day before the Republican National Convention?
- 3.) When did Dr. Hahn learn that there would be a press event to make the announcement at the White House on Sunday? What were the challenges for him getting to that event?

- 4.) When did the FDA decide to use the statistic that plasma had shown a "35% improvement in survival for patients?" Who briefed Sec. Azar and President Trump on the statistic?
- 5.) What has Dr. Hahn learned from this experience about communicating health information to the public and the appearance of political influence on FDA decisions? Does he plan to approach future FDA announcements any differently, if so, how?
- 6.) Many former FDA officials have told the AP that Dr. Hahn's misstatement has damaged the FDA's reputation at a critical time. Do you agree or disagree? Does Dr. Hahn have any plans or ideas to repair FDA's public image in the weeks and months ahead? If so, can you give us some examples of what we should expect to see?
- 7.) Would Dr. Hahn ever consider overruling FDA staff if he disagrees with their conclusion about the safety and efficacy of a vaccine? Under what circumstances would he use his authority to reverse an FDA staff decision on a COVID-19 vaccine?
- 8.) The Health and Human Secretary Alex Azar has the legal authority to overrule Dr. Hahn on the final determination about a EUA or BLA for a vaccine. Dr. Peter Marks has publicly committed to resign if he is forced to authorize or approve an inadequate vaccine. Will Dr. Hahn do the same? Why or why not?

Matthew Perrone AP Health Writer (202) 641-9863 mperrone@ap.org @AP_FDAwriter

The Associated Press, founded in 1846, is the essential global news network, delivering fast, unbiased news from every corner of the world to all media platforms and formats. With a network of 240 bureaus, AP is the largest and most trusted source of independent news and information, providing content to more than 15,000 news outlets. On any given day, more than half the world's population sees news from AP.

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 3:58:38 PM

To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP

Wolf – will you please make Caputo and WH comms and PPO this is coming? Buckham said he was planning on this kind of story but I don't know what he was planning to do. OR I can send to them but I don't want to make this about me. It should be about what's best to keep the Commissioner's reputation solid.

-EM

Call/text (b) (6)

From: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:57 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: RE: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP

Agree that HHS and WH should be made aware. Not sure they would recommend responding especially after the hit piece on Hahn again this am.

From: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Tuesday, August 25, 2020 3:51 PM

To: Wagner, John < John.Wolf.Wagner@fda.hhs.gov >; Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov >

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: STORY ON ME -- Wolf/Emily: STAT story on FDA, deadline ASAP

Wolf and Keagan, We need to at least send this to Caputo and WH to see if they want to chime in here? I'm not concerned for my reputation but for Dr. Hahn appear to being "handled" by WH and conservative right wing nut (me) so maybe we can tramp down that narrative?

-EM

Call/text (b) (6)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:46 PM **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Subject: FW: Wolf/Emily: STAT story on FDA, deadline ASAP

Stephanie Caccomo

Media Relations Director

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: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:41 PM

To: Caccomo, Stephanie <Stephanie <Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: RE: Wolf/Emily: STAT story on FDA, deadline ASAP

You think? 😊

Wow....

John 'Wolf' Wagner

Associate Commissioner

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Sent: Tuesday, August 25, 2020 3:41 PM

To: Wagner, John < John.Wolf.Wagner@fda.hhs.gov>; Miller, Emily < Emily.Miller@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov >

Subject: Wolf/Emily: STAT story on FDA, deadline ASAP

Hi-

Do you want us to decline to comment?

Stephanie Caccomo

Media Relations Director

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: Lev Facher < lev.facher@statnews.com Sent: Tuesday, August 25, 2020 3:05 PM

To: FDA Office of Media Affairs < FDAOMA@FDA.HHS.GOV >; Miller, Emily < Emily.Miller@fda.hhs.gov >; Felberbaum,

Michael < Michael. Felberbaum@fda.hhs.gov>; Wagner, John < John.Wolf. Wagner@fda.hhs.gov>

Cc: Nicholas Florko < <u>nicholas.florko@statnews.com</u>>
Subject: Re: STAT story on FDA, deadline ASAP

All:

We're running another piece tomorrow on several administration moves perceived as undercutting the FDA, which include:

- -Concern within FDA's own ranks, citing three senior FDA officials, about Emily Miller's role and past writings on gun rights, transgender health issues, and Obamacare ads on birth control (one headlne in a Washington Times column:
- "New Obamacare ads make young women look like sluts," many others)
- -The president's "deep state" tweet
- -The appointment of David Gortler, who advocated for a mass firing FDA in a STAT op-ed a few years ago
- -The political tint to Sunday's briefing re: the plasma EUA

We'd like to request an **interview with Dr. Hahn** regarding the last several days' events, personnel shifts at FDA, flagging morale within the agency, and our forthcoming story's reporting that senior FDA officials believe Dr. Hahn should be doing more to combat the White House's actions that, intentionally or not, have damaged the agency's reputation and undercut its authority.

Please feel free to reach out anytime this evening to respond to any of the themes above or discuss scheduling an interview with the commissioner.

Lev

On Tue, Aug 25, 2020 at 11:09 AM FDA Office of Media Affairs <FDAOMA@fda.hhs.gov> wrote:

Good Morning,

Please reference the below link for the most recent information on this subject. We'll be sure to flag any additional information for you when it is available.

 $\frac{https://www.cbsnews.com/video/fda-commissioner-hahn-responds-to-criticism-about-politicization-of-covid-19-treatment-authorization/\#x$

Thank you.

From: Lev Facher < lev.facher@statnews.com Sent: Monday, August 24, 2020 4:30 PM

To: FDA Office of Media Affairs < FDAOMA@FDA.HHS.GOV >; Miller, Emily < Emily.Miller@fda.hhs.gov >

Cc: Nicholas Florko <nicholas.florko@statnews.com>

Subject: STAT story on FDA, deadline ASAP

All: Lev with STAT here. My colleague Nick Florko and I are running a story tomorrow that raises questions about Commissioner Hahn's ability to resist political pressure at FDA and steer the agency through uncertain times amid Covid. It makes a number of points below, on which we'd love FDA's response if possible. Thanks in advance for your help: I'm available at (510)-374-8880.

- -Commissioner Hahn has no experience in government, and has just a small circle of FDA advisors on whom he relies heavily: Anand Shah, Jeet Guram, Colin Rom, and Lowell Zeta. Collectively, these folks have minimal experience in FDA leadership.
- -Commissioner Hahn's claim last night that of "100 people who are sick with Covid-19 35 would have been saved" makes two hugely significant errors which the FDA has not recanted: The source of the 35% mortality reduction statistic, itself is unclear to many outside experts, and even if it's correct, it of course doesn't "save" 35% percent of all Covid patients; it reduces the mortality by 35%.
- -Unlike past commissioners, Dr. Hahn does not have significant relationships with the former commissioners (though we quote an outside voice explaining that he is a) a political outsider and b) has mostly run the agency during a pandemic, i.e., this is to be expected.)
- -Emily, your role is typically not one filled by a political appointee.

-The story doesn't include voices questioning the science underpinning the plasma EUA -- only the presentation of the decision, which people viewed as highly politicized.

--

Lev Facher Washington Correspondent

Cell/Signal/WhatsApp: (510) 374-8880

@levfacher

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Lev Facher Washington Correspondent

Cell/Signal/WhatsApp: (510) 374-8880

@levfacher

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(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 12:04:30 PM

To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

Subject: Accepted: Press Paper SOP/Media Inquiries ** SOP Attached **

Location: Webex

Start: 8/26/2020 1:00:00 PM **End**: 8/26/2020 1:30:00 PM

Show Time As: Busy

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 10:24:59 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: Declined: Press Paper clearance ***attaching current press officer SOP

Start: 8/26/2020 8:30:00 AM **End**: 8/26/2020 9:00:00 AM

Show Time As: Free

Recurrence: (none)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 6:23:32 PM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: Media memo to SH tonight

Do you have a draft yet that I can see so we can get to him? This has to be exactly what he asked us for today.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Call/text: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/28/2020 8:54:12 AM

To: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Hunt, Alison

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Tantibanchachai, Chanapa [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5b7147258d46b3a5d1f6c8d90bd3ac-Chan.Tantib]

Subject: RE: // FOR APPROVAL // FDA Media Inquiry – Wired – hydroxychloroquine shortage - 11:00 a.m. 8/28

I clear. Move to the rest of clearance please.

-EM

Call/text (b) (6)

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Thursday, August 27, 2020 10:03 PM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>; Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>

Cc: Tantibanchachai, Chanapa < Chanapa. Tantibanchachai@fda.hhs.gov>

Subject: RE: // FOR APPROVAL // FDA Media Inquiry - Wired - hydroxychloroquine shortage - 11:00 a.m. 8/28

Substance-wise, this response looks good to me. It's a straightforward answer that provides transparency — confirming dates that the drugs were on the shortage list. Even if reporter's angle is politically motivated, I recommend we respond straight with a just-the-facts answer. No spin.

I don't know when OCC reviews, but we will make sure they do if they haven't already.

From: Miller, Emily < Emily.Miller@fda.hhs.gov>

Date: August 27, 2020 at 9:26:05 PM EDT

To: Hunt, Alison <Alison.Hunt@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>, Tantibanchachai, Chanapa

<Chanapa.Tantibanchachai@fda.hhs.gov>

Subject: RE: // FOR APPROVAL // FDA Media Inquiry – Wired – hydroxychloroquine shortage - 11:00 a.m. 8/28

Alison-Tight turn around time – if it's for print, can you find out why they asked late at night before? Can you see if they have an angle on this we're missing that's political?

Also is the response on background or quote from spokesman/woman?

Defer to Shannon on substance of it.

Shannon- do these things go through OCC approval before getting to me or do I send them?

From: Hunt, Alison < Alison.Hunt@fda.hhs.gov>

Sent: Thursday, August 27, 2020 8:29 PM

To: Wagner, John < John. Wolf. Wagner @fda.hhs.gov >; Miller, Emily < Emily. Miller @fda.hhs.gov >

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Tantibanchachai, Chanapa

<Chanapa.Tantibanchachai@fda.hhs.gov>

Subject: // FOR APPROVAL // FDA Media Inquiry - Wired - hydroxychloroquine shortage - 11:00 a.m. 8/28

Reporter: Adam Rogers
Outlet: Wired (print mag)
Deadline: 11 a.m., 8/28

Background:

I'm writing a story for Wired's print edition about hydroxychloroquine and Covid-19, and I'm hoping to understand a bit more about the shortages of chloroquine and hydroxychloroquine that happened in early and mid-March.

Questions:

The kind of publicity and attention that came from Silicon Valley and political leadership didn't really get high-pitched and intense until the third week of March; do you have a sense of what led physicians to start prescribing the drugs that led to those shortages? Was it hospital use? Confined to a specific region, largely? Or use by individuals?

According to the folks at Sandoz, some time in early March as part of a regular call, DSS asked Sandoz about the availability of hydroxychloroquine. That led to Sandoz donating 30 million doses of the drug to the national stockpile. Was that normal for a response to a shortage?

Proposed response:



Expected place of publication: Print edition of Wired

Expected date of publication: TBD

Expected prominence: TBD

Alison Hunt, MPH

Press Officer

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration

Desk: 240.402.0764

Cell: (b) (6) Bldg: 32, Room 5341 alison.hunt@fda.hhs.gov











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 7:26:29 PM

To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]

Subject: Accepted: Touch Base with Commissioner, COS, & Dep Commissioner Shah

Location: 1-877-465-7975, (b) (6)

Start: 8/26/2020 5:45:00 PM **End**: 8/26/2020 6:15:00 PM

Show Time As: Busy

Recurrence: (none)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 10:36:32 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: Jonathan Swan

You have his cell?

Also lets hold off on more emails about this week with the group. Ask me but everyone is jazzed up about the apology tweet and cbs so we want everyone to TAKE A DEEP BREATH and focus on this only

Then we drown them in other stuff

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Monday, August 24, 2020 10:29 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Jonathan Swan

Jonathan Swan < jonathan@axios.com>

Stephanie Caccomo

Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

8/25/2020 2:22:49 PM Sent:

To: Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]; Felberbaum, Michael

[/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Wagner, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]

CC: Hatch, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

RE: FOR APPROVAL// FDA Media Inquiry – Law 360- Legislation for Mandatory Drug Recalls- Deadline 8/25 1pm Subject:

That's helpful. I would like to give commissioner options to comment if he wants on things like this so when we have an inquiry, can you talk to the offices and see if it's something we're helping or have supported so I can tell him about the option?

-EM

Call/text (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 12:04 PM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Miller, Emily <Emily.Miller@fda.hhs.gov>; Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>

Cc: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: FOR APPROVAL// FDA Media Inquiry – Law 360- Legislation for Mandatory Drug Recalls- Deadline 8/25 1pm

For background, there have been a number of these same bills introduced over the years, including one recently in February. Generally the agency is on board with expanding recall authority, but I've never seen it relayed publicly on paper except for maybe an off the cuff comment by Dr. Woodcock in an interview. I think the leg and CDER teams would need a few days to digest this newest bill before providing their thoughts to us.

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











From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 11:59 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>; Wagner, John

<John.Wolf.Wagner@fda.hhs.gov>

Cc: Hatch, Shannon < Shannon.Hatch@fda.hhs.gov >; Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov > Subject: RE: FOR APPROVAL// FDA Media Inquiry — Law 360- Legislation for Mandatory Drug Recalls- Deadline 8/25 1pm

Traditionally we do not comment on pending legislation as a policy matter. Our leg teams work directly with Hill staff to provide input and technical assistance.

From: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Tuesday, August 25, 2020 11:54 AM

To: Kahn, Jeremy < Jeremy . Kahn@fda.hhs.gov >; Wagner, John < John. Wolf. Wagner@fda.hhs.gov >

Cc: Hatch, Shannon < Shannon. Hatch @fda.hhs.gov>; Caccomo, Stephanie < Stephanie. Caccomo @fda.hhs.gov>;

Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov >

Subject: RE: FOR APPROVAL// FDA Media Inquiry – Law 360- Legislation for Mandatory Drug Recalls- Deadline 8/25 1pm

Can you check with leg affairs if we have been supportive of this bill? If this is a something we want, then we should be on the record supporting the concept, if not the actual bill, right?

-EM

Call/text (b) (6)

From: Kahn, Jeremy < Jeremy.Kahn@fda.hhs.gov >

Sent: Tuesday, August 25, 2020 11:52 AM

To: Wagner, John < John. Wolf. Wagner @fda.hhs.gov>

Cc: Miller, Emily < Emily. Miller@fda.hhs.gov >; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov >; Caccomo, Stephanie

<<u>Stephanie.Caccomo@fda.hhs.gov</u>>; Felberbaum, Michael <<u>Michael.Felberbaum@fda.hhs.gov</u>>

Subject: FOR APPROVAL// FDA Media Inquiry - Law 360- Legislation for Mandatory Drug Recalls- Deadline 8/25 1pm

Media Inquiry Request

Reporter: Adam Lidgett

Media Outlet: Law 360

FDA Spokespersons: FDA written response, attribution FDA spokesperson

Subject: Legislation for Mandatory Drug Recalls

Deadline: 8/25 1p

Expected place of publication (print, online, broadcast): Online

Expected date of publication/airing: 8/25 1:30p

Background:

I'm doing a story on Sen. Gary Peters introducing legislation that would grant the U.S. Food and Drug Administration the authority to recall unsafe drugs. I was looking to see if you had a comment on that.

Response:

On-the-record:

The FDA generally does not comment on proposed or pending legislation.

On Background:

Patient safety is the FDA's top priority. As of October 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act gives the FDA the authority to issue a mandatory recall order for any controlled substance if there is a reasonable probability that the controlled substance would cause serious adverse health consequences or death.

However, FDA does not have the authority to issue a mandatory recall for other drug substances. Under the Federal Food, Drug, and Cosmetic Act, a recall is a voluntary action taken by a company to remove a defective drug product from the market. Voluntary drug recalls may be conducted on a company's own initiative or by FDA request. FDA's role in a recall is to oversee a company's strategy, assess the adequacy of the recall and classify the recall. If a company does not issue public notification of a recall, FDA may do so if the agency determines it is necessary to protect patients.

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











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 6:23:30 PM

To: Sanchez-Contreras, Gloria [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c873214d26584af0a22cf4121d3630f7-Gloria.Sanc]

CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Kimberly, Brad

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]

Subject: RE: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

No to any interviews that Hahn has not personally approved.

-EM

Call/text (b) (6)

From: Sanchez-Contreras, Gloria <Gloria.Sanchez-Contreras@fda.hhs.gov>

Sent: Thursday, August 27, 2020 3:52 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Subject: RE: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

Hi Emily,

I need to let get back to the reporter below about this interview. Is this approve to send to ASPA for clearance now?

Thank you,

Gloria

From: Sanchez-Contreras, Gloria

Sent: Wednesday, August 26, 2020 4:19 PM **To:** Miller, Emily < Emily.Miller@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Subject: RE: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

Sure, I can pull a list of reporters for these areas and make a pitch. Just let me know what the TPs and strategy are and happy to help with the Spanish-language media outreach.

In the meantime, can I move to clear the interview below?

Gloria

From: Miller, Emily < Emily.Miller@fda.hhs.gov >

Sent: Wednesday, August 26, 2020 4:09 PM

To: Sanchez-Contreras, Gloria < Gloria. Sanchez-Contreras@fda.hhs.gov>

Cc: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >; Kimberly, Brad < Brad.Kimberly@fda.hhs.gov >

Subject: RE: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

We are so slammed with all the required embers cities each week. Do you have a Spanish speaking outlet in Texas to use because we are on Dallas and Corpus this week. I have many reporters I like at Univision and Telemundo TV in Texas so if you want to pitch one of them? Or I think we will get Houston next week and can do that.

-EM

Call/text (b) (6)

From: Sanchez-Contreras, Gloria < Gloria. Sanchez-Contreras@fda.hhs.gov >

Sent: Wednesday, August 26, 2020 4:05 PM **To:** Miller, Emily <<u>Emily.Miller@fda.hhs.gov</u>>

Cc: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >; Kimberly, Brad < Brad.Kimberly@fda.hhs.gov >

Subject: FW: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

Hi Emily,

You might know that I serve as the Spanish-language spokesperson for the Agency. Please see the media request below and let me know if I can send it for ASPA clearance.

I have also been doing educational COVID-19 interviews with regional Spanish-language TV and radio stations. Wolf and Anthony Cruz in the White House have been approving these interviews. Here is a link for a recent interview about food safety and coronavirus: https://www.telemundo20.com/noticias/local/como-protegerse-en-el-supermercado/2012898/

Let me know if you have any questions.

Thank you,

Gloria

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 3:57 PM

To: Sanchez-Contreras, Gloria < Gloria. Sanchez-Contreras@fda.hhs.gov>; Hatch, Shannon

<Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Kimberly, Brad

<Brad.Kimberly@fda.hhs.gov>

Cc: Cassell, Peter < Peter. Cassell@fda.hhs.gov>

Subject: RE: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

Ok—can you please get Emily ok? Worth explaining your role here.

Stephanie Caccomo

Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956

stephanie.caccomo@fda.hhs.gov

From: Sanchez-Contreras, Gloria < Gloria. Sanchez-Contreras@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 3:44 PM

To: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>; Hatch, Shannon < Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov>; Kimberly, Brad < Brad.Kimberly@fda.hhs.gov>

Cc: Cassell, Peter < Peter. Cassell@fda.hhs.gov>

Subject: Univision Radio Miami Phone Interview Request (Spanish): Onion Recalls

Hi all,

Please let me know if I can send the interview request below for ASPA clearance or if it needs to be cleared by Emily. This is cleared language from our website, and Peter has reviewed it

Thank you,

Gloria

ASPA Media Interview Request

Reporter: Ana Restifo

Organization: Buenos Días América, Univision Network Radio (live phone interview)

Contact information: (b) (6) / (b) (6)

Subject: Recalls

Deadline: August 27, 2020

FDA Spokespersons: Gloria Sanchez, bilingual public affairs specialist

Expected place of publication (print, online, broadcast): Spanish-language radio

Expected date of publication/airing: September

Expected prominence (e.g. front page, Sunday, evening/morning show, etc.): Moring news

Key messages/talking points:

Key messages/talking points:





Onions Recall

On August 1, 2020, Thomson International, Inc. recalled all varieties of onions that could have come in contact with potentially contaminated red onions, due to the risk of cross-contamination. Recalled products include red, yellow, white, and sweet yellow onions shipped from May 1, 2020 to August 1, 2020. Onions were distributed to wholesalers, restaurants, and retail stores in all 50 states, the District of Columbia and Canada.

Consumers who have symptoms should contact their health care provider to report their symptoms and receive care.

To report a complaint or adverse event (illness or serious allergic reaction), you can

To report problems or get more information please visit: www.fda.gov or call 1-888-INFO-FDA (1-888-463-6332)

Gloria Sánchez-Contreras

International Press Officer Spanish-Language Communications Lead

Office of Media Affairs Office of External Affairs U.S. Food and Drug Administration Tel: 301-796-7686 / Cell: (b) (6) gloria.sanchez-contreras@fda.hhs.gov









(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 3:40:03 PM

To: Emily Miller (b) (6)

Subject: Fwd: Keagan--responses on Emily's position

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Caccomo, Stephanie Stephanie Caccomo@fda.hhs.gov>

Date: August 26, 2020 at 3:14:49 PM EDT

To: Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov>

Cc: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>, Miller, Emily < Emily. Miller@fda.hhs.gov>,

Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>, Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Subject: Keagan--responses on Emily's position

Keagan-

In response to the negative swirl, we want to send below to Daily Caller about Emily. Ok with you?

On background from FDA:

Ms. Miller was hired effective July 24, after a formal interview process with agency and department leadership. The Office of Media Affairs has not had a permanent Assistant Commissioner since March 2020. Two individuals have acted as head of the office in the interim. Both individuals are still at FDA.

Ms. Miller was brought to the FDA to lead a well-established group of public affairs professionals.

Her biography: https://www.fda.gov/about-fda/fda-organization/emily-miller

Stephanie Caccomo

Media Relations Director

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: Miller, Emily < Emily Miller@fda.hhs.gov Sent: Wednesday, August 26, 2020 2:03 PM

To: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>;

Kimberly, Brad < Brad Brad.Kimberly@fda.hhs.gov Subject: RE: Wolf--responses on Emily's position

The contact at Daily Caller is Henry Rogers. He won't do the story because I taught him Sunday school so it's a conflict. But he's going to assign to another reporter. This is his email – hrodgers@dailycaller.com

Cell is (b) (6)

When you (or whoever makes the contact with the Caller) talks to him, can you also send the link to my bio online—should be up soon.

Everything below is great. Thank you so much. I really appreciate the team support here. I want this narrative fixed so we can get back to independent agency that is not political.

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >

Sent: Wednesday, August 26, 2020 1:46 PM

To: Wagner, John < John. Wolf. Wagner @fda.hhs.gov>

Cc: Miller, Emily <Emily.Miller@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hatch,

Shannon <Shannon.Hatch@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Subject: Wolf--responses on Emily's position

Wolf updated to just include you! Plus updated outlet.

Salon has posted a very negative story about Emily. Reporter had some additional questions. Proposed below response to Salon, but Emily has connected with Daily Caller. Might be more beneficial to send to Daily Caller to ensure an accurate story

Ok with below?

Questions from Salon (can plan to provide to a friendly outlet):

Did someone from the administration reach out to you about this position?

Yes, I was called by the White House in May while I was working for a Texas government coronavirus task force to consider a job at the FDA.

Did you speak with Michael Caputo ahead of your hiring?

I spoke to him after I was hired. I had never met him prior to starting at FDA

How do you reconcile your time at a pro-Trump news outlet with your public service employment?

I have openly supported President Trump since I first wrote an opinion piece about his potential in 2012 in The Washington Times. I interviewed him many times between 2012 and a week before he was elected in 2016. https://www.washingtontimes.com/news/2012/sep/3/the-trump-factor/

I have not talked to him since he was elected president.

When were you hired? Who was former Acting Asst Commissioner, and where are they now?

I spoke to the White House in May and said I would move back to DC for this position at the FDA. I don't know who was acting at the time. I interviewed with Dr. Hahn in June. The acting head is taking a position with the Principal Deputy Commissioner to advise on communication matters but has been enormously helpful to me in transitioning over the media office.

On background from FDA:

Ms. Miller started at the FDA on Aug. 16, after a formal interview process with agency and department leadership. The Office of Media Affairs has not had a permanent Assistant Commissioner since March 2020. Two individuals have acted as head of the office in the interim. Both individuals are still at FDA.

Ms. Miller was brought to the FDA to lead a well-established group of public affairs professionals.

Quote from Dr. Hahn:

Emily Miller is exceptional communications professional who is dedicated to serving the FDA's mission during this unprecedented global pandemic. She will ensure our communications are clear, thoughtful and convey the FDA's important work fighting this pandemic.

Stephanie Caccomo

Media Relations Director

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

FDA-OC- OMA COMS Aug20P1

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/24/2020 5:00:49 PM

To: 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]

Subject: FW: NYT backlash- deadline

Please forward to marks press person and staff who I don't know ...

From: Miller, Emily

Sent: Monday, August 24, 2020 5:00 PM **To:** Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>; Caccomo, Stephanie

<Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov> Subject: NYT backlash- deadline

Peter – See below from NYT. Can your staff answer any of these questions? Our quote seems to have stirred them up worse and want to give them anything else we have on hand as a solid answer.

From: Katie Thomas < katie.thomas@nytimes.com >

Sent: Monday, August 24, 2020 4:54 PM

To: Miller, Emily < Emily.Miller@fda.hhs.gov >; Sheri Fink < sheri.fink@nytimes.com >

Cc: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Subject: Re: FW: NYT Qs for story on 35% figure

This doesn't answer my questions.

- --Why was this particular figure used multiple times by President Trump and two top health officials but doesn't appear in the FDA decision memorandum or in any of the backup documents? Will this data be published?
- --we were initially directed by Stephanie to page 12, figure 3 of of the EUA application, which cited the Mayo Clinic preprint. Is that now incorrect, and the source should be an FDA analysis of the EAP data? We were also directed to a slide that indicated a 37 percent (not 35 percent) reduction, of a different patient group. Again, is that not in fact the source of their 35 percent claim?
- --does Dr. Hahn stand by his statement that 35 out of 100 sick Covid-19 patients would not have died... several researchers have said none of the available data supports this and one said there's almost no drug in existence that can make this claim. Researchers who have done the math say they believe that 4 out of 100 sick patients' lives may have been saved... and also that he confused absolute vs relative risk reduction. Is he planning on correcting his statements?

Katie Thomas Staff Writer, New York Times

Twitter: @katie_thomas

On Mon, Aug 24, 2020 at 3:19 PM Miller, Emily <Emily.Miller@fda.hhs.gov> wrote:

Below is an on the record quote below is from Dr. Peter Marks, Director of the FDA Center for Biological Evaluation and Research:

"FDA reviewed data from multiple sources, including over a dozen published studies, as well as the prepublication data from the Mayo Clinic. We also conducted our own analysis of the data from the national Expanded Access Program for COVID-19 convalescent plasma. Note that in the Expanded Access Program, the antibody titer of the plasma given to patients was not known until after patients were treated, potentially reducing any bias. Although the effect size with the administration of COVID-19 convalescent plasma varies somewhat from study to study, likely in part to the different populations treated, the FDA notes that there appears to be roughly a 35 percent relative improvement in the survival rates of patients who were treated with higher titer plasma when compared to those treated with lower titer plasma. Given the safety profile observed, the totality of evidence regarding potential efficacy more than adequately met the 'may be effective' standard for granting an Emergency Use Authorization."

From: Katie Thomas <katie.thomas@nytimes.com>

Sent: Monday, August 24, 2020 11:26 AM

To: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov >

Subject: 35 percent figure

Hi Stephanie,

Thanks for taking my call this morning. As I mentioned, we're working on a story following up on the 35 percent figure that was cited by President Trump, Mr. Azar, and Dr. Hahn and also tweeted by the FDA account.

1) I would like to talk to someone at the F.D.A. who can walk me through why this particular statistic was selected as the main one to highlight, and where, specifically it came from.

The Figure 3 you directed me to last night from the EUA application, as you know, was not in the FDA's decision memo, and was buried deep in the document, on page 12. The 35 percent figure is also not included -- they are lines on a graph.

The slide you then shared does not match the statements from Dr. Marks yesterday, when he referred to 30 day mortality -- the slide says 7 day mortality. Which is correct?

One of the main authors of the preprint said this morning he does not know where that 35 percent came from.

2) Several clinical trial specialists have said that in his comments, Dr. Hahn confused absolute risk reduction with relative risk reduction. He said: "35% improvement in survival is a pretty substantial clinical benefit. What that means is if the data continue to pan out, 100 people who are sick with COVID-19, 35 would have been saved because of the administration of plasma." He repeated the similar claims later in his speech.

Several experts have said this is untrue, is an exaggeration and also a "rudimentary" error. They say the data in the Mayo Clinic preprint do not support this, and have called on Dr. Hahn to correct himself, including Robert Califf, the former FDA commissioner. Can you comment on this?
Finishing the story ASAP today
Katie
Katie Thomas
Staff Writer, New York Times
(b) (6) Twitter: @katie_thomas

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE1

Sent: 8/26/2020 12:02:51 PM

To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]

Subject: RE: Press Paper SOP/Media Inquiries ** SOP Attached **

And will Heidi know what Keagan said on Monday so we don't keep going in circles?

Basically on Monday, I was told by White House that I do not send anything to Hahn for approval and the only chain of command for public/press documents and interviews is to Wolf to Caputo. I've repeatedly asked Wolf about how he wants to do that with the system in place and he hasn't responded.

-EM

Call/text (b) (6)

From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 11:57 AM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: RE: Press Paper SOP/Media Inquiries ** SOP Attached **

Wolf has accepted and Keagan asked Heidi to attend this meeting on her behalf.

From: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Wednesday, August 26, 2020 11:51 AM

To: Felberbaum, Michael < Michael.Felberbaum@fda.hhs.gov Subject: Re: Press Paper SOP/Media Inquiries ** SOP Attached **

Keagan and wolf have to be on this call if we do it. So make sure they are on it. If not, do a new time when they can. The meeting we had in person on this Monday isn't going to work and they need to know.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Felberbaum, Michael < Michael. Felberbaum@fda.hhs.gov>

When: August 26, 2020 at 1:00:00 PM EDT

Required: Miller, Emily < Emily. Miller@fda.hhs.gov >, Lenihan, Keagan < Keagan. Lenihan@fda.hhs.gov >, Wagner,

John \(\)John. \(\)Wolf. \(\)Wagner \(\)Gda. \(\)hs. gov \(\), \(\) Hatch, \(\)Shannon \(\)Shannon \(\)Hatch \(\)Gda. \(\)hs. gov \(\), \(\)Amin, \(\)Stacy

<Stacy.Amin@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Optional: Raza, Mark Mark Raza@fda.hhs.gov, Rebello, Heidi Heidi Rebello@fda.hhs.gov, Kimberly, Brad

<Brad.Kimberly@fda.hhs.gov>

Subject: Press Paper SOP/Media Inquiries ** SOP Attached **

Location: Webex

Meeting Purpose: Overview of established SOP (attached) that predictably and efficiently allows for FDA press paper to be reviewed and cleared by appropriate parties for technical and legal accuracy. We will also discuss media inquiry clearance.

1-210-795-0506 US Toll

+1-877-465-7975 US Toll Free Access code: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 10:24:48 PM

To: Broderick, Brianna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c2403f4adae453ca6efd28044ddef37-BRODERICKB]

Subject: Declined: Rescheduled - Records Mgmt Briefing

Location: Webex

Start: 8/26/2020 10:00:00 AM **End**: 8/26/2020 10:30:00 AM

Show Time As: Free

Recurrence: (none)

I have my staff meeting at this time and I run it.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 7:26:07 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: Re: FDA Commissioner interview on vaccine/plasma, Friday?

If you don't hear back (reporters never look at email) I have cell for all these guys and will give you to call or text. Just text me names on my other phone bc my contacts are all on there.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Date: August 26, 2020 at 5:58:05 PM EDT

To: jmoritz@gannett.com <jmoritz@gannett.com> **Cc:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: FDA Commissioner interview on vaccine/plasma, Friday?

Hi John-

Reaching out to see if we can find 15 minutes for you and FDA Commissioner Stephen Hahn to connect early Friday AM to talk about our recent convalescent plasma authorization as well as the latest on vaccine development. Do you have time tomorrow to chat for a few minutes about this? Would really like to make this happen!

Thanks! Stephanie

Stephanie Caccomo

Media Relations Director

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

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/27/2020 11:19:09 PM

To: Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; Hatch, Shannon

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8815c6c081c4d2f90133732b483bc28-Shannon.Hat]; Caccomo, Stephanie

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: Some things that didn't make clips:

Never could see the story. Can we find out what is the FDA comms account for WSJ and other outlets? If we don't have one, there are government ones so let's ask HHS for theirs.

-EM

Call/text (b) (6)

From: Wagner, John < John. Wolf. Wagner@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 8:02 AM

To: Miller, Emily <Emily.Miller@fda.hhs.gov>; Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Walsh, Sandy

<Sandy.Walsh@fda.hhs.gov>

Subject: RE: Some things that didn't make clips:

Can someone pull the full stories please from the paywalls?

Thanks!

John 'Wolf' Wagner Associate Commissioner

From: Wagner, John

Sent: Wednesday, August 26, 2020 7:46 AM

To: Miller, Emily < Emily. Miller@fda.hhs.gov>; Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>; Stephanie Caccomo (Stephanie.Caccomo@fda.hhs.gov)

<<u>Stephanie.Caccomo@fda.hhs.gov</u>>; Walsh, Sandy <<u>Sandy.Walsh@fda.hhs.gov</u>>

Cc: Lenihan, Keagan < Keagan.Lenihan@fda.hhs.gov>; Shah, Anand < Anand.Shah@fda.hhs.gov>

Subject: Some things that didn't make clips:

https://www.washingtonpost.com/business/2020/08/26/biz-fda-hahn/

https://www.axios.com/fda-coronavirus-trump-political-pressure-7e6136b2-fc79-488c-93de-2dc052bacf40.html

https://www.sfchronicle.com/opinion/editorials/article/Editorial-Trump-s-political-lean-on-FDA-for-15514652.php

https://www.wsj.com/articles/fda-officials-reject-claims-that-convalescent-plasma-decision-was-politicized-11598362563?mod=e2tw&utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

John 'Wolf' Wagner Associate Commissioner Office of External Affairs
U.S. Food and Drug Administration
john.wolf.wagner@fda.hhs.gov



(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 6:11:38 PM

To: Drew Armstrong [darmstrong17@bloomberg.net]

Subject: Re: Story text

Definitely agree that it's like reading someone's journal. It's rare to see it done that way and it's so interesting. I leaned more about his thinking!

Sure on tv. We have to wait a bit since you got this exclusive but def understand your audience has a bigger interest than ever in FDA.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Drew Armstrong (BLOOMBERG/ NEWSROOM:) darmstrong17@bloomberg.net

Date: August 25, 2020 at 5:11:17 PM EDT **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: Re: Story text

He's great. I always like doing these Q&A formats when somebody is legitimately in the news like he is, and is willing to answer questions candidly (like he did). Their voice is usually more interesting than mine, and it gives the readers a lot. Happy to do this type of thing more often, and I will also do this on TV for us if you guys are open in the future.

Drew Armstrong Senior Editor, Health Care Bloomberg News 212.617.8933 (o)

@ArmstrongDrew (t)

From: Emily.Miller@fda.hhs.gov At: 08/25/20 17:05:49

To: Drew Armstrong (BLOOMBERG/ NEWSROOM:)

Subject: Re: Story text

Thank you. He's really genuine as you can tell now that you've talked to him. No angles.

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

From: Drew Armstrong (BLOOMBERG/ NEWSROOM:) vdarmstrong17@bloomberg.net

Date: August 25, 2020 at 4:58:36 PM EDT

To: Miller, Emily < Emily. Miller@fda.hhs.gov>

Subject: Story text

(Bloomberg) --

The U.S. Food and Drug Administration is facing controversy after its commissioner, Stephen Hahn, substantially overstated the benefits of an experimental therapy for Covid-19 patients.

In a press conference with Trump, Hahn said the therapy — blood plasma from recovered patients — could save 35 of every 100 people who would have died. Those high-profile remarks were incorrect, and they were repeated by others in the Trump administration. Hahn late Monday clarified some of what the data on blood plasma actually show.

But the episode has raised questions about how the agency will review a vaccine, as well as its scientific independence as Trump's reelection hinges on his response to the virus.

Bloomberg spoke to Hahn by phone. The conversation has been edited and condensed for clarity.

Bloomberg: You've taken a lot of criticism and scrutiny over the 48 hours since the press conference with the president. What's that been like? Hahn: It's been a challenge. The thing that has been the most challenging, has been trying to get out the public health message. A lot of things have happened in the last two weeks regarding convalescent plasma. And I think the convergence of all of those things created the impression of political interference. That's the biggest concern because I have complete trust in the scientists at FDA.

Bloomberg: You're a highly trained doctor and researcher. But your quote at the press conference about 35 out of 100 people being saved by this therapy when the benefit is far less, how did that mistake happen? (The data the FDA looked at was two categories of plasma — a higher dose, and a lower one. It only compared how one group did against another, now how great the benefit was versus a placebo.)

Hahn: I was trying to do what I do with patients, because patients often understand things in absolute terms versus relative terms. And I should've been more careful, there's no question about it. What I was trying to get to is that if you look at a hundred patients who receive high titre, and a hundred patients who received low titre, the difference between those two particular subset of patients who had these specific criteria was a 35% reduction in mortality. So I frankly did not do a good job of explaining that

Bloomberg: What was the internal reaction at the FDA to your error? Hahn: We've had frank discussions about it. We're sorting those out. I am going to have to correct that and I'm going to have to accept the fact that I made a mistake and own it. I think that's the first start.

Bloomberg: Other people in the administration have taken your misstatement and repeated it. Have you asked them to take those statements down or correct them?

Hahn: I have not spent time talking to others in the administration about this. I did have a conversation with [Health and Human Services] Secretary [Alex] Azar about this. I feel like my job is just to clarify from an FDA point of view, what we meant. The White House is aware of my attempts to clarify the situation. But other than that I have not had any additional conversations.

Blomberg: What happened in your conversation with Azar?

Hahn: We just discussed this issue and making sure that the right information is out there.

Bloomberg: It's an incredibly political time, and people are already inclined to distrust what they hear. Do you worry that the public perception of the FDA has been hurt by this?

Hahn: Absolutely, I worry about that. I can only hope that being honest and straightforward lessens that impact. But as you mentioned, we're in an incredibly politicized time, and these are really difficult concepts to explain to the American people.

At the end of the day, I know my patients never cared about relative versus absolute benefits. They just wanted to understand if the juice is worth the squeeze. The totality of data was in support of a promising benefit and safety.

Bloomberg: Do you worry making blood plasma more widely available will make it harder to get patients into clinical trials? If I'm a Covid-19 patient, why would I sign up for a trial and maybe get a placebo?

Hahn: Yeah, I do worry about it. We aren't going to be able to twist doctor's arms to enroll their patients. The gold standard of a randomized trial would be incredibly helpful here. We may find that the benefit goes away with more data. If that happens, we're going to reevaluate our EUA.

Bloomberg: President Trump has been a proponent of drugs like

hydroxychloroquine, even after the FDA pulled back an emergency authorization when it was found not to be helpful. Do you feel that political pressure and that it could happen with other products?

Hahn: Yeah, I'm aware of it. I've listened to all the conversations. But what I tell internally our folks is they need to make the decisions based upon the data. I have not reversed one of their decisions, nor do I intend to unless I think it's absolutely wrong. So, yeah, I listen to it, but it's not going to change what we do.

Bloomberg: There was a report by Reuters that Peter Marks, who leads the group in the FDA that reviews vaccines, would resign if the agency approved a vaccine without enough safety and efficacy data. Did he say that?

Hahn: Peter did not say that to me. But it wouldn't surprise me that that is accurate.

Bloomberg: What would you, personally, do if you felt like you were being asked to rubber-stamp a vaccine?

Hahn: I'm not going to speculate, other than to tell you that it would not be okay for me and I would not participate in any decision that was made any on anything other than the science.

Bloomberg: There was another report, by Axios, that White House adviser Peter Navarro told some FDA officials that ""You are all Deep State and you need to get on Trump Time," accusing the agency of slowing down work to hurt the president politically. Did that happen?

Hahn: I was not present for that comment. I have heard it reported. I just don't know when or if occurred. What I can tell you is that I feel very strongly that the 17,000-plus FDA employees are true professionals. None of them wants to delay getting medical products into the hands of Americans.

Bloomberg: What level of evidence is needed to get a vaccine into people's hands, for example on an emergency basis to an at-risk group? More than for blood plasma, or for hydroxychloroquine?

Hahn: Remember a vaccine is given to healthy individuals. So it's a different clinical circumstance than giving plasma to hospitalized, sick patients. That has to be considered in the decision making.

Bloomberg: Do you think the FDA has more political independence because of its public health role? Should it? And has that changed at all?

Hahn: The FDA is often caught in the middle of a lot of different conversations. It's magnified because we're in a significant public health crisis. And what FDA does in a public health crisis is to try to get medical products to address that crisis. FDA always feels under a microscope with respect to its decisions. It's never gonna make all people

Bloomberg: Do you think the FDA should be an independent agency, like the Federal Reserve, instead of part of the Health and Human Services Department?

Hahn: I hadn't really thought about that.

happy.

Bloomberg: It might sound good right now.

Hahn: I hadn't really thought about that. I think it's worth consideration, because of the issues that we're talking about. So I don't really have a stance on it because I haven't put much thought into it. I don't want to rush into giving you an opinion about it.

Blomberg: Have you grappled with the possibility that you'll have vaccine data right before, or right after, election day, and how you'll handle that?

Hahn: Of course I've thought about it. We've been thinking about this, frankly, since the spring and early summer.

It's why we put out vaccine guidance on June 30th, because we wanted to put our marker down. We wanted folks to know what we're going to need to see from a safety, efficacy, patient, or volunteer population point of view. It's why we feel so strongly about having a vaccine advisory committee review the data with us. And we spent a lot of time internally thinking about how can we adjust our processes to make sure it's all hands on deck when we receive the data.

Bloomberg: Do you think it's realistic to have a vaccine in the hands of patients by then?

Hahn: I'm a cancer doctor. I tell my patients I don't have a crystal ball, and I most definitely do not have a crystal ball here. I don't think it would be prudent for me to speculate on that because I just don't know.

Drew Armstrong Senior Editor, Health Care Bloomberg News 212.617.8933 (o) (b) (6)

@ArmstrongDrew (t)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/26/2020 12:00:44 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

Thank you for that. I'm going to ignore them for now then 🔾

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 12:00 PM **To:** Miller, Emily <Emily.Miller@fda.hhs.gov>

Subject: RE: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

This email does not go external. This particular daily email chain is a "night note" to HHS about what is happening the next day. More of a planning doc.

Stephanie Caccomo

Media Relations Director

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: Miller, Emily < Emilto:Emily.Miller@fda.hhs.gov Sent: Wednesday, August 26, 2020 11:53 AM

To: Caccomo, Stephanie < Stephanie.Caccomo@fda.hhs.gov>

Subject: RE: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

Press papers don't go to media, right? This is very technical.

-EM

Call/text (b) (6)

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 11:29 AM

To: Hatch, Shannon <Shannon.Hatch@fda.hhs.gov>; Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Braithwaite, Sonia

- <<u>Sonia.Braithwaite@fda.hhs.gov</u>>; Cooper, Mildred <<u>Mildred.Cooper@fda.hhs.gov</u>>; Cristinzio, Dayle
- <Dayle.Cristinzio@fda.hhs.gov>; Fritsch, Beth F. <Beth.Fritsch@fda.hhs.gov>; Mulieri, Chris
- <Charles.Mulieri@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; Setthachayanon, Nick
- <Nick.Setthachayanon@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander

<Alexander.Wohl@fda.hhs.gov>

Subject: RE: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

Topic: FDA issues notice of 'Vaccines and Related Biological Products Advisory Committee' (VRBPAC) in Federal

Register

Details: FDA is announcing a forthcoming public advisory committee meeting of the VRBPAC. The meeting will be held on

Oct. 22, 2020. The committee will discuss the development and licensure of vaccines to prevent COVID-19.

Target: THURSDAY Center/Office: CBER

POC: Media: Brittney Manchester Materials: Press Release, Tweets

Stephanie Caccomo

Media Relations Director

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stephanie.caccomo@fda.hhs.gov

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov >

Sent: Wednesday, August 26, 2020 11:19 AM

To: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov >; Wasserman, Jill < Jill. Wasserman@fda.hhs.gov >; Braithwaite, Sonia

- <Sonia.Braithwaite@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Cristinzio, Dayle
- <Dayle.Cristinzio@fda.hhs.gov>; Fritsch, Beth F. <Beth.Fritsch@fda.hhs.gov>; Mulieri, Chris
- < Charles. Mulieri@fda.hhs.gov >; OMA Leadership < OMALeadership@fda.hhs.gov >; Setthachayanon, Nick
- <Nick.Setthachayanon@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander

<Alexander.Wohl@fda.hhs.gov>

Subject: RE: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

There is a PR going tomorrow on the vaccine advisory committee. Will find language asap

Stephanie Caccomo

Media Relations Director

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

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stephanie.caccomo@fda.hhs.gov

From: Hatch, Shannon < Shannon. Hatch@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 11:16 AM

To: Wasserman, Jill Jill.Wasserman@fda.hhs.gov; Braithwaite, Sonia Sonia.Braithwaite@fda.hhs.gov; Cooper,

Mildred <Mildred.Cooper@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Fritsch, Beth F.

<Beth.Fritsch@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; OMA Leadership

<OMALeadership@fda.hhs.gov>; Setthachayanon, Nick <Nick.Setthachayanon@fda.hhs.gov>; Walsh, Sandy

<<u>Sandy.Walsh@fda.hhs.gov</u>>; Wohl, Alexander <<u>A</u>lexander.Wohl@fda.hhs.gov>

Subject: RE: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

No additions from me. Thanks, Jill!

Shannon P. Hatch

Media Relations Director

Office of Media Affairs
Office of External Affairs
Mobile: (b) (6)

From: Wasserman, Jill < Jill. Wasserman@fda.hhs.gov>

Sent: Wednesday, August 26, 2020 11:13 AM

To: Braithwaite, Sonia <Sonia.Braithwaite@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Cristinzio,

Dayle <code>Dayle.Cristinzio@fda.hhs.gov></code>; Fritsch, Beth F. ; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; OMA Leadership <OMALeadership@fda.hhs.gov>; Setthachayanon, Nick <Nick.Setthachayanon@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander < Alexander. Wohl@fda.hhs.gov>

Subject: Please Review by 1/1:30pm: DRAFT Press Paper for Thursday, August 27

Below is the DRAFT press paper update for Thursday, August 27. Please let me know if there are any revisions, etc. Thank you -Jill

PRESS PAPER:

COVID-19 Daily Roundup

NOTES:

Tweets on safety communication for cold-induced injuries when using the cold-therapy mode of watercirculating hot/cold therapy devices

FDA is informing consumers and health care professionals of the risk of cold-induced injuries when using the coldtherapy mode of water-circulating hot/cold therapy devices. Potential injuries include numbness, discoloration, freezing of skin and underlying tissue, and tissue cell death, which at times requires skin grafts, muscle/skin flaps, or amputation. When used correctly, these devices

Jill Wasserman, MPH Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration Work Cell: (b) (6) Jill.Wasserman@fda.hhs.gov











(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 11:21:52 AM

To: Palmer, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1efe882d2038426faf0ecb4c8bbbe020-PALMERK]

Subject: Declined: Records Management Briefing with Emily Miller

Location: WebEx

Start: 8/25/2020 2:00:00 PM **End**: 8/25/2020 2:30:00 PM

Show Time As: Free

Recurrence: (none)

Wolf Wagner told me not to do this today

Emily Miller

FDA Assistant Commissioner for Media Affairs

Text/call: (b) (6)

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=349EA636FE504B488ADF664E48CE87E6-EMILY.MILLE]

Sent: 8/25/2020 3:54:57 PM

To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: RE: Press Paper clearance

What does this mean?

-EM

Call/text (b) (6)

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

From: Caccomo, Stephanie < Stephanie. Caccomo@fda.hhs.gov>

Sent: Tuesday, August 25, 2020 3:35 PM

To: Hatch, Shannon; Miller, Emily; Wagner, John

Subject: Press Paper clearance

When: Friday, August 28, 2020 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where:

(b)(5) DRAFT

(b)(5) DRAFT

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE August 26, 2020

COVID-19 Update: FDA Warns Consumers about Hand Sanitizer Packaged in Food and Drink Containers

Silver Spring, MD --- The U.S. Food and Drug Administration (FDA) is warning consumers about [HYPERLINK "https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19"] that are being packaged in containers that may appear as food or drinks and may put consumers at risk of serious injury or death if ingested. The agency has discovered that some hand sanitizers are being packaged in beer cans, children's food pouches, water bottles, juice bottles and vodka bottles. Additionally, the FDA has found hand sanitizers that contain food flavors, such as chocolate or raspberry.

"I am increasingly concerned about hand sanitizer being packaged to appear to be consumable products, such as baby food or beverages. These products could confuse consumers into accidentally ingesting a potentially deadly product. It's dangerous to add scents with food flavors to hand sanitizers which children could think smells like food, eat and get alcohol poisoning," said FDA Commissioner Stephen M. Hahn, M.D. "Manufacturers should be vigilant about packaging and marketing their hand sanitizers in food or drink packages in an effort to mitigate any potential inadvertent use by consumers. The FDA continues to monitor these products and we'll take appropriate actions as needed to protect the health of Americans."

In one recent example of consumer confusion, the FDA received a report that a consumer purchased a bottle they thought to be drinking water but was in fact hand sanitizer. The agency also received a report from a retailer about a hand sanitizer product marketed with cartoons for children that was in a pouch that resembles a snack. Drinking only a small amount of hand sanitizer is potentially lethal to a young child, who may be attracted by a pleasant smell or brightly colored bottle of hand sanitizer.

Hand sanitizer can be toxic when ingested. The FDA continues to see an increasing number of adverse events with hand sanitizer ingestion, including cardiac effects, effects on the central nervous system, hospitalizations and death, primarily reported to poison control centers and state departments of health. For more information, consumers should refer to the FDA's guidelines on [HYPERLINK "https://www.fda.gov/consumers/consumer-updates/safely-using-hand-sanitizer"] as well as [HYPERLINK "https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19"].

The FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's [HYPERLINK "https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program" \o "MedWatch: The FDA Safety Information and Adverse Event Reporting Program"] program (please provide the agency with as much information to identify the product as possible.)

The FDA continues to proactively work with manufacturers to recall potentially dangerous hand sanitizer products and is strongly encouraging retailers to remove these products from store shelves and online marketplaces. A [HYPERLINK "https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol" \I "products"] of hand sanitizer products that the FDA urges consumers to avoid, along with a description for consumers on how to use the list, has been posted to the agency's website, which is being updated regularly.

###

Consumer Inquiries: [HYPERLINK "mailto:covid-19-hand-sanitizers@fda.hhs.gov"] or 888-INFO-FDA

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.