From: Callahan, Victoria (OS) [Victoria.Callahan@hhs.gov]
Sent: 3/31/2020 5:06:56 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sanderson, Tyler (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62abd856ddb5453b925ae8545159397a-HHS-Tyler.S]; Beattie, Allison (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4364f0b8edb1404c8ccb0c55c138a8b3-HHS-Allison]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Johnson, Kelly J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=379c7c00b4354a28b7b8f8a8c5960d12-HHS-Kelly.J]; Siviy, Kayla [ksiviy@umaryland.edu]; Siviy, Kayla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300059d28b94176bb020e51d6d30480-HHS-Kayla.S]; jeffrey.goodie@usuhs.edu

Subject: COVID-19 Departmental Action Group
Location: Teleconfernece Number: 8003204330,,(b) (6)

Start: 4/1/2020 2:30:00 PM
End: 4/1/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore

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(b) (6) [redacted], Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sanderson, Tyler (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62abd856ddb5453b925ae8545159397a-HHS-Tyler.S]; Beattie, Allison (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4364f0b8edb1404c8ccb0c55c138a8b3-HHS-Allison]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Johnson, Kelly J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=379c7c00b4354a28b7b8f8a8c5960d12-HHS-Kelly.J]; Siviy, Kayla [ksiviy@umaryland.edu]; Siviy, Kayla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300059d28b94176bb020e51d6d30480-HHS-Kayla.S]; jeffrey.goodie@usuhs.edu

Subject: COVID-19 Departmental Action Group
Attachments: COVID-19 Departmental Action Group
Location: Teleconfernece Number: 8003204330, (b) (6)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sanderson, Tyler (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=62abd856ddb5453b925ae8545159397a-HHS-Tyler.S]; Beattie, Allison (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4364f0b8edb1404c8ccb0c55c138a8b3-HHS-Allison]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Johnson, Kelly J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=379c7c00b4354a28b7b8f8a8c5960d12-HHS-Kelly.J]; Siviy, Kayla [ksiviy@umaryland.edu]; Siviy, Kayla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300059d28b94176bb020e51d6d30480-HHS-Kayla.S]; jeffrey.goodie@usuhs.edu

Subject: COVID-19 Departmental Action Group
Attachments: COVID-19 Departmental Action Group
Location: Teleconfernece Number: 8003204330, (b) (6)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Callahan, Victoria (OS) [Victoria.Callahan@hhs.gov]
Sent: 3/31/2020 5:06:56 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey

(IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) ; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sanderson, Tyler (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=62abd856ddb5453b925ae8545159397a-HHS-Tyler.S]; Beattie, Allison (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4364f0b8edb1404c8ccb0c55c138a8b3-HHS-Allison]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Johnson, Kelly J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=379c7c00b4354a28b7b8f8a8c5960d12-HHS-Kelly.J]; Siviy, Kayla [ksiviy@umaryland.edu]; Siviy, Kayla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300059d28b94176bb020e51d6d30480-HHS-Kayla.S]; jeffrey.goodie@usuhs.edu

Subject: COVID-19 Departmental Action Group
Location: Teleconfernece Number: 8003204330,,(b) (6)

Start: 4/1/2020 2:30:00 PM
End: 4/1/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore

(SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith

(b) (6) , Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sanderson, Tyler (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62abd856ddb5453b925ae8545159397a-HHS-Tyler.S]; Beattie, Allison (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4364f0b8edb1404c8ccb0c55c138a8b3-HHS-Allison]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Johnson, Kelly J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=379c7c00b4354a28b7b8f8a8c5960d12-HHS-Kelly.J]; Siviy, Kayla [ksiviy@umaryland.edu]; Siviy, Kayla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300059d28b94176bb020e51d6d30480-HHS-Kayla.S]; jeffrey.goodie@usuhs.edu

Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: Teleconfernece Number: 8003204330,,(b) (6)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

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Start: 4/1/2020 2:30:00 PM
End: 4/1/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith ([redacted] Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sanderson, Tyler (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62abd856ddb5453b925ae8545159397a-HHS-Tyler.S]; Beattie, Allison (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4364f0b8edb1404c8ccb0c55c138a8b3-HHS-Allison]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Tatem, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5222c26605ef4894a8d237d82fd1ba6f-HHS-Anne.Ta]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Johnson, Kelly J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=379c7c00b4354a28b7b8f8a8c5960d12-HHS-Kelly.J]; Siviy, Kayla [ksiviy@umaryland.edu]; Siviy, Kayla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300059d28b94176bb020e51d6d30480-HHS-Kayla.S]; jeffrey.goodie@usuhs.edu

Subject: COVID-19 Departmental Action Group
Location: Teleconfernece Number: 8003204330,,,437474

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6)]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly

Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/3/2020 1:58:07 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1 (b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-H (b) (6)]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011- (b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344 (b) (6); Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Windom, Robert (OS/ASPR/IO) [Robert.Windom@hhs.gov]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]

Subject: COVID-19 Advisory Panel
Location: WEBEx - 2027742300,,(b) (6)

Start: 4/5/2020 4:00:00 PM
End: 4/5/2020 5:00:00 PM
Show Time As: Tentative

Recurrence: (none)

- BARDA will present their portfolio and clear guidance

(Material/slide presentation forthcoming)

Hi Arwenthia Ford-Barnes,

Arwenthia Ford-Barnes updated this WebEx meeting for which you are an alternate host:

BARDA COVID-19 Advisory Panel Portfolio (on behalf of Dr. Robert Kadlec)
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
Start the meeting

When: Sunday, April 5, 2020, 4:00 pm (1 hr), Eastern Daylight Time (New York, GMT-04:00).

Access Information

Meeting Number:
(b) (6)

Password:
(This meeting does not require a password.)

Host Key:
(b) (6) Use this key during the meeting if you ever need to reclaim the host role.)

Audio Connection

2027742300 (Meeting Server Main Number)

Access Code:
(b) (6)

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Please excuse this mass email. I want to convey my greetings and best wishes from the Secretary who asked me to convene the Department's best people form CDC, NIH and FDA to periodically review, provide feedback and guidance to BARDA's COVID-19 MCM portfolio. I would expect this would be virtual and require read aheads providing detail of prospective programs in vaccines, therapeutics, diagnostics and potential medical devices. I would anticipate a first meeting in April and quarterly after that.

The challenge is you are all extremely busy and the only way this works is provide materials well in advance and conduct a substantive meeting in 60-75 minutes. I have had the chance to speak to some but not all of you and I apologize if I haven yet personally reached out to you on this topic. Again I appreciate your potential interest and willingness to help support a national crisis and national investment in finding safe and effective countermeasures. Best Bob

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/3/2020 1:58:07 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; (b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS- (b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a- (b) (6)]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011- (b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344-HHS-Vanessa]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Kemp, Micha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37e66d7934924dbbb481f43a55477be7-HHS-Micha.K]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Windom, Robert (OS/ASPR/IO) [Robert.Windom@hhs.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4- (b) (6) Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]

Subject: COVID-19 Advisory Panel
Attachments: BARDA COVID Vaccines White Paper 20200405b.docx; BARDA COVID Portfolio Review 20200405b.pptx
Location: WEBEx - 2027742300,,(b) (6)

Start: 4/5/2020 3:45:00 PM
End: 4/5/2020 4:45:00 PM
Show Time As: Busy

Recurrence: (none)

AGENDA
Introduction by Dr Kadlec, ASPR
BARDA:

- Overall COVID-19 Strategy & Plan
- Activities to Date (e.g. industry outreach, RFP BAA etc.)
- High level overview of current MCM portfolio
- Detailed briefing of current vaccine technical development efforts, timeline and costs

Discussion by participants
Summary of follow-on actions

Updated materials:

Hi Arwenthia Ford-Barnes,

Arwenthia Ford-Barnes updated this WebEx meeting for which you are an alternate host:

BARDA COVID-19 Advisory Panel Portfolio (on behalf of Dr. Robert Kadlec)
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
Start the meeting

When: Sunday, April 5, 2020, 4:00 pm (1 hr), Eastern Daylight Time (New York, GMT-04:00).

Access Information

Meeting Number:
(b) (6)

Password:
(This meeting does not require a password.)

Host Key:
(b) (6) (Use this key during the meeting if you ever need to reclaim the host role.)

Audio Connection

2027742300 (Meeting Server Main Number)

Access Code:
(b) (6)

Delivering the power of collaboration
The meetingserver.hhs.gov team

Please excuse this mass email. I want to convey my greetings and best wishes from the Secretary who asked me to convene the Department's best people form CDC, NIH and FDA to periodically review, provide feedback and guidance to BARDA's COVID-19 MCM portfolio. I would expect this would be virtual and require read aheads providing detail of prospective programs in vaccines, therapeutics, diagnostics and potential medical devices. I would anticipate a first meeting in April and quarterly after that.

The challenge is you are all extremely busy and the only way this works is provide materials well in advance and conduct a substantive meeting in 60-75 minutes. I have had the chance to speak to some but not all of you and I apologize if I haven yet personally reached out to you on this topic. Again I appreciate your potential interest and willingness to help support a national crisis and national investment in finding safe and effective countermeasures. Best Bob

PREPARING THE NATION:

ACCELERATING 2019-nCoV VACCINE DEVELOPMENT

I. BACKGROUND

Developing and delivering a vaccine for a fast-moving emerging infectious disease such as COVID-19 requires breaking from traditional development approaches. It requires an aggressive, multi-candidate approach, with parallel development activity streams, aggressive manufacturing scale-up, risk management, and taking full advantage of regulatory flexibilities. Furthermore, it requires sufficient funding to incentivize manufacturing partners to go 'all in' to prioritize time, capabilities, collaboration, resources, and accept lost opportunity costs from other profitable options.

When assessing potential vaccine candidates, while each are different, certain desirable attributes are shared. Each vaccine candidate represents a 'platform' or proven technology that has been evaluated in clinical trials for other infectious diseases. This approach de-risks and accelerates multiple aspects of vaccine development. At a minimum, early manufacturing steps are defined and significant planning can be done for manufacturing scale-up and process validation. Each platform will have human safety and immunogenicity data targeting an infectious agent.

It is critical that the vaccine be produced in the United States. Domestic production of the vaccine is the only assurance that Americans will have access to the finished product. Contractual terms will include domestic production requirements and a strong emphasis to source materials through a US supply chain. Candidates meeting the desired profile of proven platform technologies, potential for rapid clinical development, and approaches for scale-up have been identified. Current development is proceeding largely at the traditional, slower pace due to lack of the significant incentives to allocate the sizable resources required to develop these vaccines at maximum speed. USG partnership inclusive of funding and technical assistance is critical to accelerating timelines and ensuring large scale, domestic production of vaccine. Additional incentives could include commitment of substantial procurement of successful vaccine (perhaps greater incentives considered for timelines, location, sourcing) and vaccine liability coverage via the PREP Act or similar instrument as used for pandemic influenza vaccine.

A multiple 'shots on goal' approach is critical for success, as no one attribute is definitely superior to others. For example, one candidate may take longer to reach clinical trials, but may be faster to scale or have existing domestic commercial manufacturing capacity. In addition, vaccine candidates will vary in production yields, impacting the overall manufacturing capacity and reducing potential raw material supply constraints that could occur if relying on one vaccine.

II. VACCINE PORTFOLIO

Many vaccine candidates are being developed against COVID-19. Funding from a variety of organizations, as well as self-funding, is advancing these candidates into clinical trials. The BARDA portfolio has a two-pronged approach. First, support a diversified base of candidates with established manufacturing processes and clinical exposure for other disease conditions to increase the chances of success in developing a vaccine for wide-spread use, as soon as possible, and ensure the necessary domestic manufacturing capability to support vaccine production for the successful candidates. Second, continue close collaboration with both USG funded and non-USG funders to identify additional promising candidates as they move through the pipeline and identify opportunities to synergize in further development of these candidates. The current BARDA portfolio consists of:

1. **mRNA platform.** A 2019-nCoV vaccine candidate is under development by Moderna with support from NIH. This platform is being developed for both infectious diseases (e.g. Zika with BARDA) and cancer. It is immunogenic against a variety of infectious disease targets. It was the first vaccine to enter the clinic, underscoring its flexibility and diversity. Further, it has a relatively small manufacturing footprint, providing opportunities for expansion into other facilities.

   Assuming the vaccine demonstrates immunogenicity, the most significant challenges to this platform relate to safety and manufacturing experience. This platform is not currently licensed for use, and no commercial production exists. Scale up capability of the vaccine is limited. As mentioned above, scale-out is a likely approach. However, scale out comes with risk, especially given that Moderna has not previously scaled the manufacturing process.

   Finally, the supply chain could be a challenge given some of the raw materials are not widely sourced.

2. Vector-based platforms

Ad26-based platform. This proven vaccine platform is currently in advance development for Ebola and other infectious disease targets by Johnson & Johnson/ Janssen. It is a well-characterized platform that has been tested in thousands of individuals in clinical trials. The manufacturing process has been validated at commercial scale for other infectious disease vaccines and is unlikely to require changes for this vaccine. Likewise, the safety profile is well understood.

Janssen initiated work prior to receiving external funding, and as a result, initial vaccine candidate immunogenicity and manufacturing growth kinetics has been obtained. Initial data indicates good manufacturing yield from expression, which has been a challenge for some vaccines with this platform.

Vaccine production will be technology transferred to the United States. Janssen has extensive experience in this area, which is important given the short timelines. Finally, Janssen has contributed a substantial cost-share to the effort, lowering the cost of vaccine development to the USG.

Providing significant immunogenicity is obtained in clinical trials, this platform approach represents a straight-forward path to large scale production and vaccine availability. Current focus, in addition to execution of activities is shortening the timeline to first in human and manufacturing scale-up.

VSV-based platform. This recently licensed ebola vaccine utilized this platform technology. This platform demonstrates an extensive safety database and strong immunogenicity profile. Strong potential for a single dose vaccine, which would decrease time to protection following vaccination, as well as decrease manufacturing and ancillary supply requirements.

Current scale is relatively small, and the potential opportunities and timelines for scale-up are still being determined. Similarly, timelines for availability of vaccine to start the Phase I trial are still being determined.

3. **The baculovirus based recombinant protein platform.** The platform was developed by US-based Protein Sciences, Inc and acquired by Sanofi Pasteur. It is based on baculovirus-expressed proteins in insect cells. It is licensed for influenza vaccine and has domestic commercial scale manufacturing is available. In 2003, the platform was used to develop a candidate SARS vaccine. Though the vaccine did not go into the clinic, the purification process is known. Through a contract with BARDA, domestic manufacturing capabilities are being expanded. For influenza vaccines, adjuvants significantly lower the amount of protein needed to induce a strong immune response. As such, current manufacturing capability will produce a substantial number of doses.

   This vaccine will require a different purification process than that used for influenza vaccine, lengthening timelines for availability of first doses for clinical testing. Further, the vaccine will be adjuvanted. While adjuvants have been identified that can be used, inclusion into the vaccine will likely lengthen development times and increase formulation efforts.

4. **Other vaccines of potential interest.**

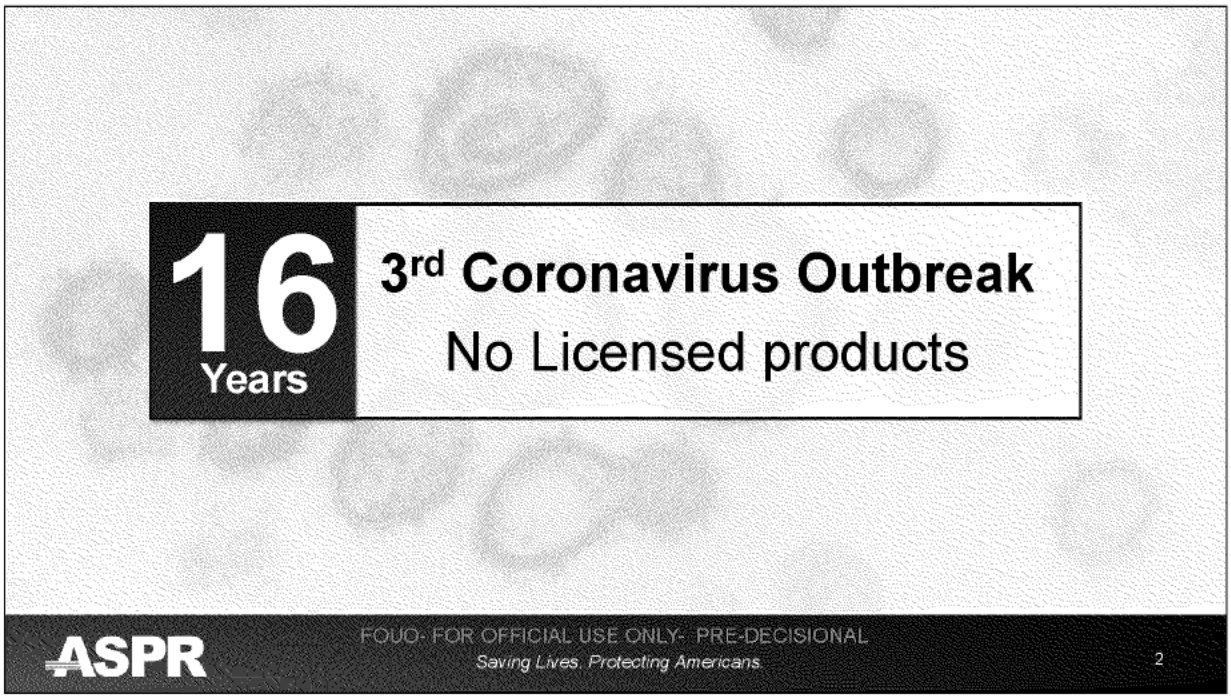
BARDA carefully tracks the multitude of other vaccines that are in development through a combination of discussions with developers, other Government agencies, and other non-USG funders, as well as evaluation of submissions to the MCM portal. These tend to have challenges in addition to those of the candidates currently funded by BARDA. This can include a) lack of scalable domestic manufacturing; b) unknown safety/immunogenicity profiles of the technology; c) lack of an adjuvant. While all of these limitations can eventually be overcome, further data is needed to determine which candidates are appropriate for further funding.

BARDA is also actively monitoring 'second wave' vaccines, which could come into play later if the virus permanently establishes itself. BARDA expects most of these candidates to come out of either direct or indirect support from NIH, and does and will continue to maintain close ties to identify opportunities at the earliest stage possible.

COVID-19 MEDICAL COUNTERMEASURE UPDATE
(FOUO, Procurement Sensitive, Pre-Decisional)
April 5, 2020

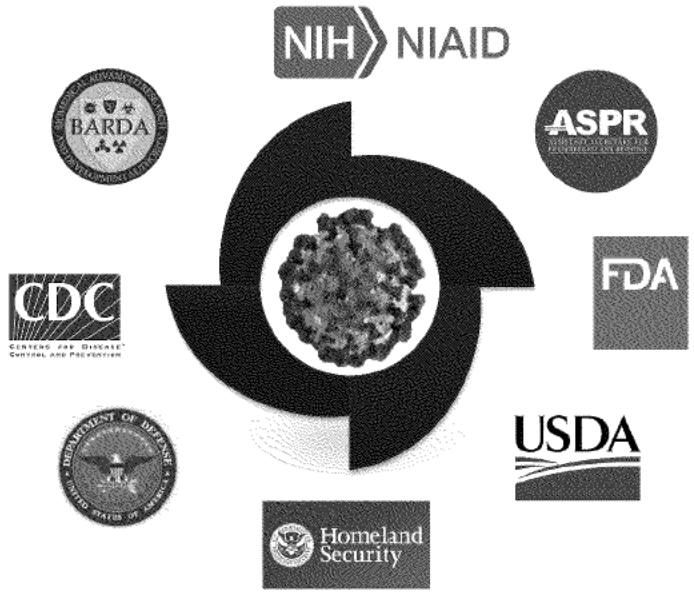
Brief to HHS Secretary Azar and HHS COVID-19 Advisory Panel, including NIH, FDA, CDC, ASPR, ASFR Leadership

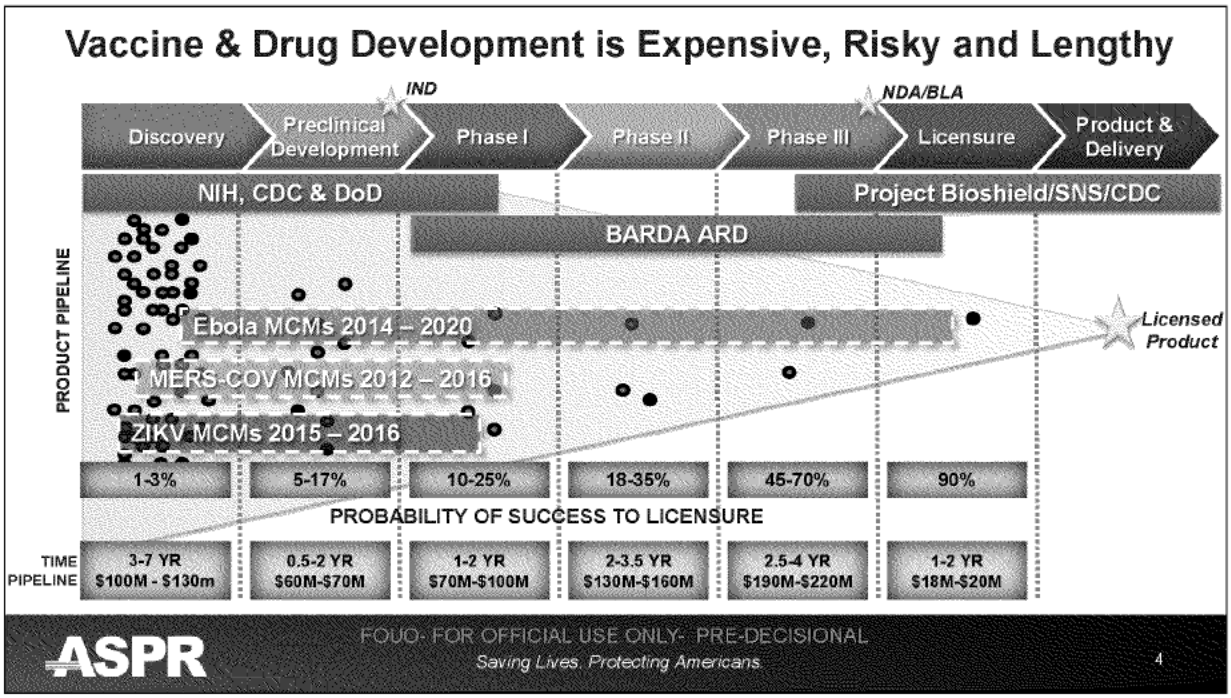
FOUO- FOR OFFICIAL USE ONLY- PRE-DECISIONAL


16
Years
3rd Coronavirus Outbreak
No Licensed products
ASPR
FOUO- FOR OFFICIAL USE ONLY- PRE-DECISIONAL
Saving Lives, Protecting Americans
2

2019-nCoV Medical Countermeasures Task Force

Align and prioritize MCM development across Interagency partners to avoid duplication of effort, identify opportunities for synergy, and fill potential gaps

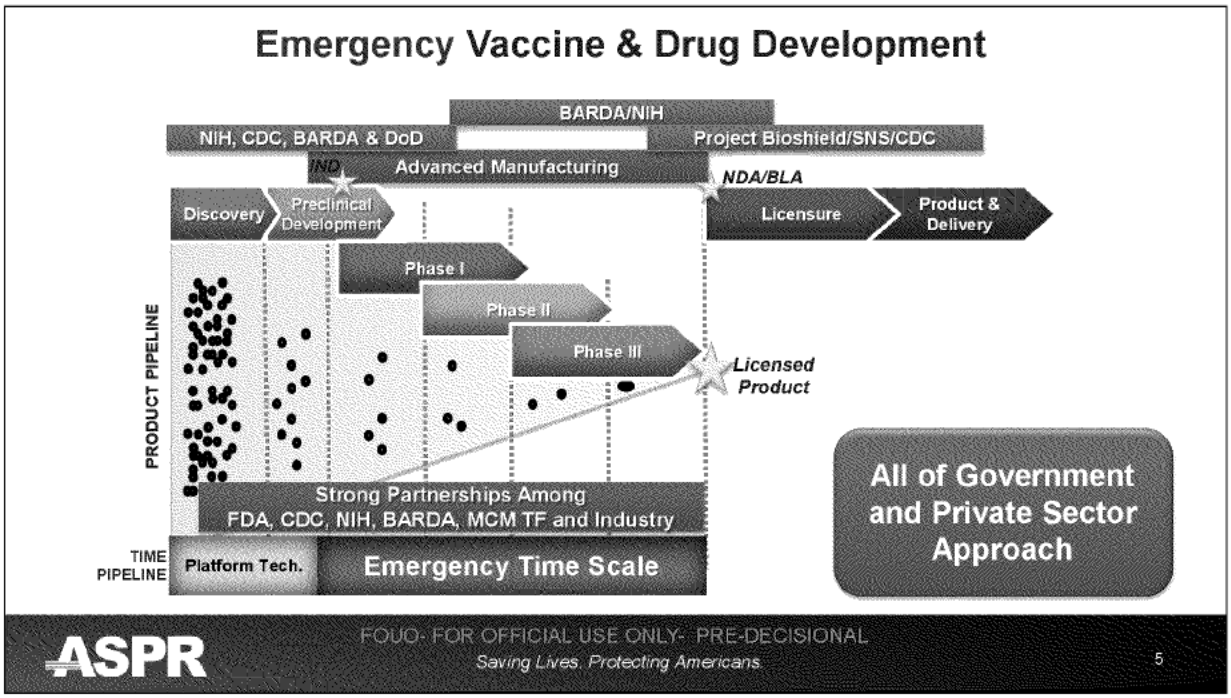




The cost to develop a drug or a vaccine is upwards of one billion dollars and the development pipeline stretches for 10-20 years.

One of the biggest challenges to moving a potential product from the discovery phase to approval is the “Valley of Death”, which happens when a product goes into expensive clinical trials.

BARDA worked with US government and private partners to support the advanced development of medical countermeasures for Ebola, MERS, and Zika while recent outbreaks were ongoing. These efforts led to the recent licensure of ERVEBO, a single dose vaccine for Ebola Zaire.



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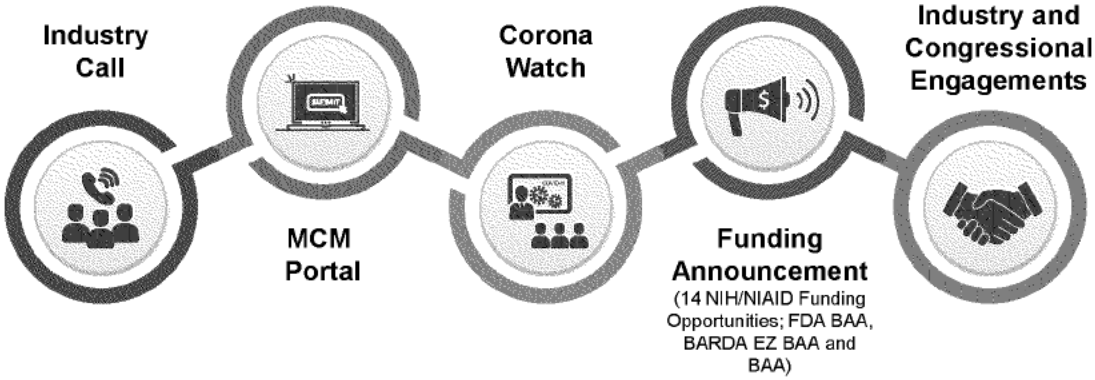
COVID-19 MEDICAL COUNTERMEASURE DEVELOPMENT STRATEGY

ACCELERATE DEVELOPMENT
- Platform technologies
- Repurpose licensed products
- Parallel, not sequential, activities

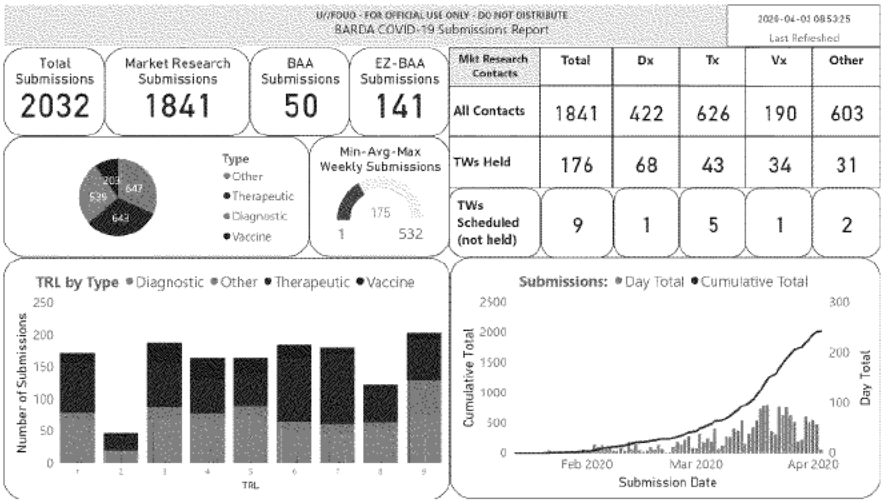
MITIGAGE RISK
- Multiple technologies
- Multiple targets
- Redundancy

DOMESTIC MANUFACTURING
- Scale Up & Scale Out
- Raw materials and supply chains
- Leverage existing facilities

Agency-Wide Engagement with Developers



COVID-19 Market Research Portal Submissions



Therapeutics Development

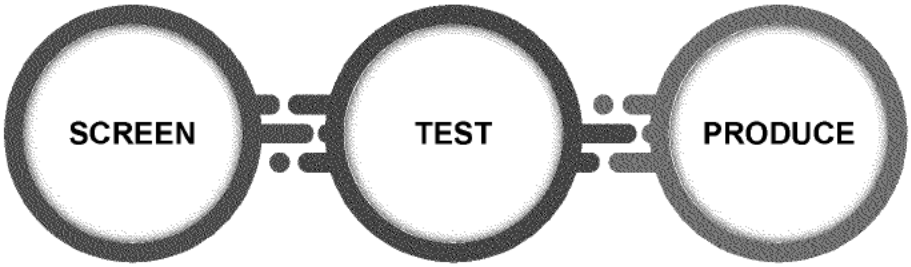
FDA-approved therapeutics licensed for other indications
- Ready for immediate clinical testing

e.g., inhibitors of viral activation, host pathway modulators

e.g., 2019-CoV specific monoclonal antibodies, small molecule antivirals, and immunoglobulins

Leverage existing infrastructure for rapid MCM generation and production through partnerships (contracts and OTA) including other USG agencies

Repurposed Therapeutics



Thousands of compounds currently being screened-low cost/high impact
Many candidates identified and undergoing clinical evaluation

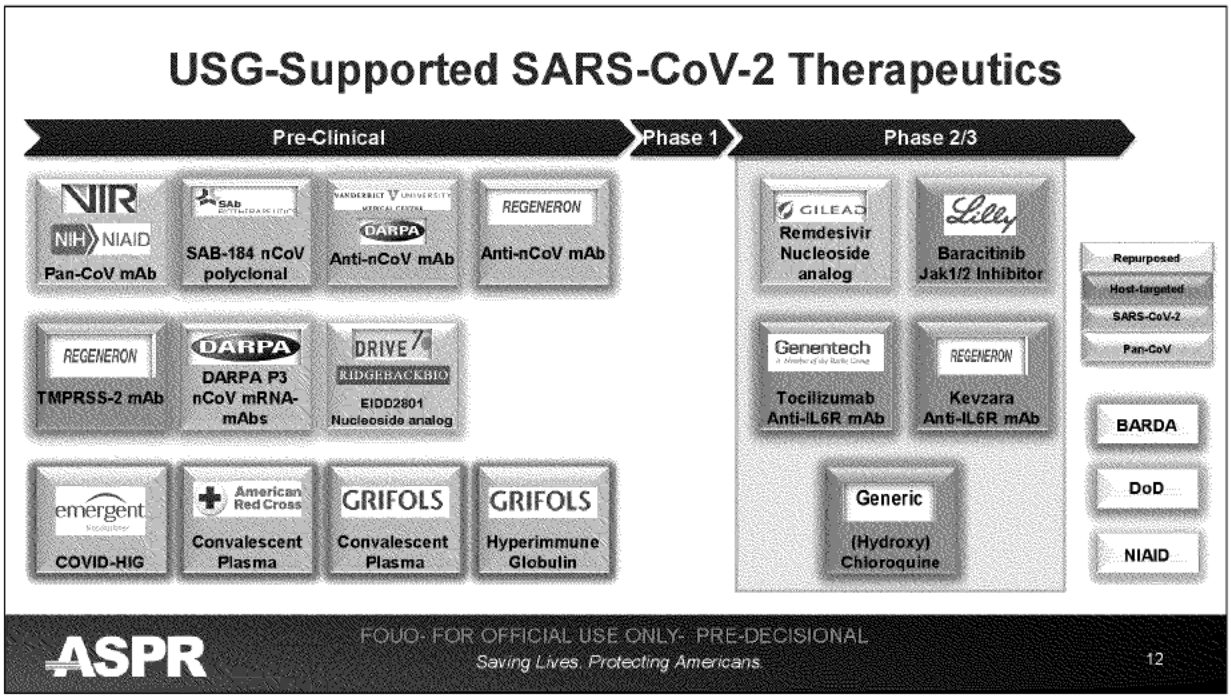
Allows rapid advancement to clinical trials (i.e. IL-6 monoclonal antibody trial started 2-weeks after identification)

Utilize existing facilities for production;
Expand capacity through partnerships with large pharmaceutical partners

BARDA seeking to leverage existing infrastructure for rapid clinical trial initiation

Therapeutics Clinical Studies: US & ROW Summary

Product Type	US Trials	US + International Trials
All therapeutics	30	231
Remdesivir	4	12
HCQ/CQ	7	46
Sarilumab (Kevzara)	1	6
Tocilizumab (Actemra)	1	10



Therapeutics
BARDA: Regeneron (Kevzara and TMPRSS2), (H)CQ, Genentech, Sab Biotherapeutics,
NIAID: Vir, DRIVE, Gilead
DoD: Therapeutic Interfering Parkticles, nCoV mRNA-mAbs, BioCryst

Vaccines
BARDA: Janssen, Sanofi Pasteur
NIAID and BARDA: Moderna
DoD: WRAIR nanoparticle, Inovio

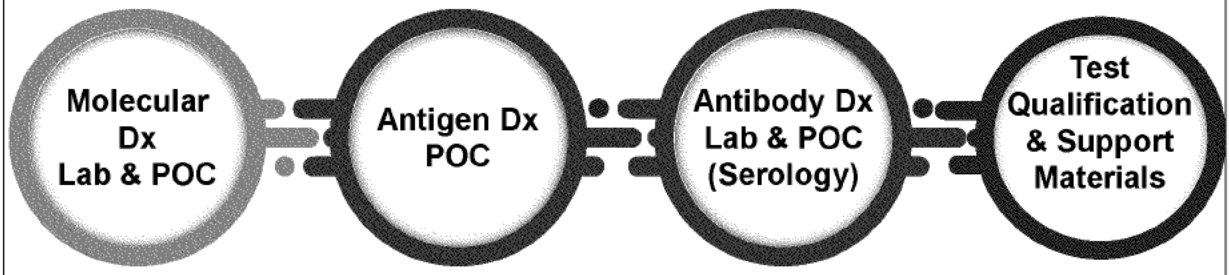
BARDA COVID-19 Therapeutic Investments

Product	Funded	Status	Future Planned Investments	Total	Notes
IL-6 Monoclonal Antibodies (Regeneron and Genentech)	$41M (plus cost share)	2 ongoing Phase III Trials	(b) (4)	(b) (4)	Repurposed products-large scale manufacturing already available
Library Screening and subsequent development (Janssen and others)	$154M	12,000+ clinically proven compounds from multiple companies undergoing high-throughput screening			
Immunoglobulin/convalescent (4 awards/4 products) (Griffols, American Red Cross, SAB, Emergent)	$35M	Convalescent plasma: Q2 2020 Expanded Access Protocol Hyperimmune: clinical trials Q2/3 2020			
ARDS Therapeutics (multiple companies)	$0	Partnering with NHLBI Networks-Trial start as soon as possible			
ARDS Prevention Therapeutics (multiple companies)	$0	Partnering with NHLBI Networks-Trial start as soon as possible			
Pepcid AC +/- hydroxychloroquine	$13M	Study start imminent			
Monoclonal Antibodies Against Virus (Regeneron and others)	$75M	Phase I/II efficacy trial Q2/3 2020			
Phlow Pharma	$340M (plus cost share)			$340M	Supports small molecule domestic manufacturing capability

BARDA / DoD / NIAID Supported Studies

Product Type	Product (Developer)	ClinicalTrials Identifier	Primary Endpoint	Target Enrollment	Current Enrollment	Number of Sites	Notes
Therapeutic	Remdesivir (Gilead)	NCT04280705	Clinical status assessed at Day 15 using 8-point ordinal scale	440 initially; increased to 700	426	49	Adaptive COVID-19 Treatment Trial; can add new candidates
Therapeutic	Sarilumab (Regeneron & Sanofi)	NCT04315298	Phase 2: Time to resolution of fever for 48h Phase 3: Time to improvement (2 points) using 7-point ordinal scale	400	730	51	Adaptive Phase 2/3 design; began enrolling March 19 and will enroll through 400[1]; patient follow up and data analysis
Therapeutic	Tolilizumab (Genentech & Roche)	NCT04320615	Clinical status assessed at Day 28 using 7-point ordinal scale	330	2	2	Phase 3 study; Scheduled to begin enrollment during the week of April 3
Vaccine	mRNA-1273 (Moderna)	NCT04283461	Safety & Immunogenicity at 25µg, 100µg & 250µg	45	30	2	Second cohort (100µg) dosed and in monitoring phase; dosing of 250µg expected to begin Apr 8
Observational	n/a	n/a	Observational study to collect pathological data on COVID-19	n/a	32	5	Department of Defense's "EPICC" Study; complementary studies in planning phases

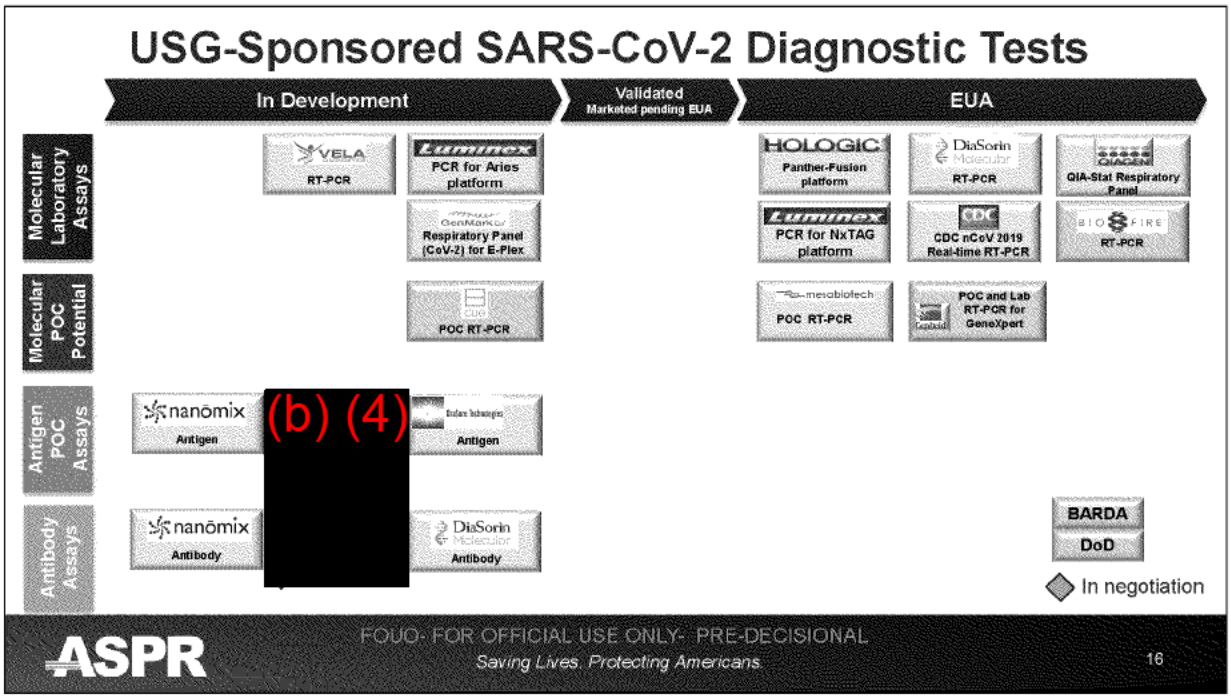
Diagnostics Development: Four-Pronged Approach



Acute Infection Determination	Acute Infection Determination (Reduced Sensitivity)	Support Return to Work	Accelerate Test Development and Regulatory Approval

Leverage existing Laboratory Infrastructure & Equipment
Leverage Existing & Complete In-Development POC Equipment

04/02/20



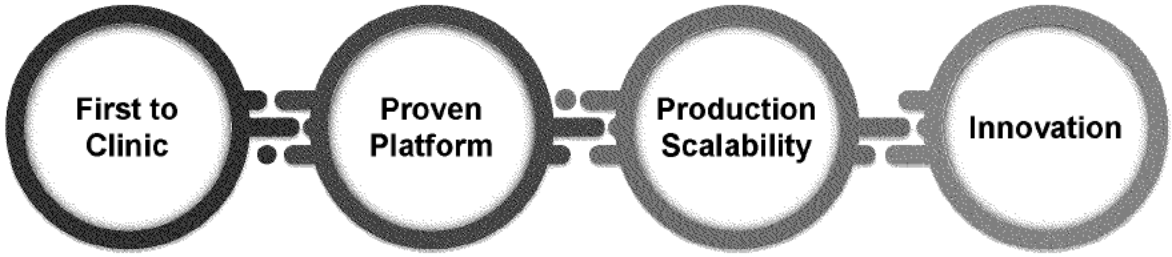
BARDA: Cue, GenMark, Vela, MesaBiotech, DiaSorin, Qiagen, Hologic, Nanomix, Hememics, DiaSorin, Orsure

DoD: Biofire

BARDA and DoD: Cepheid

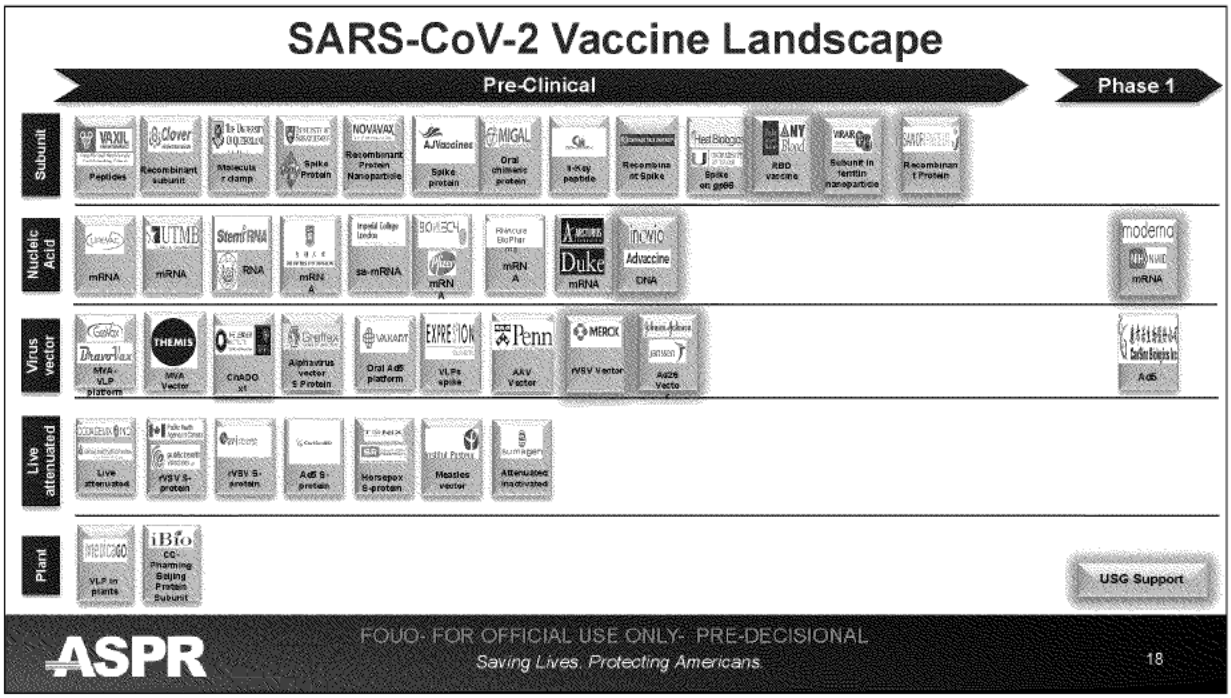
CDC: CDC

Vaccine Development



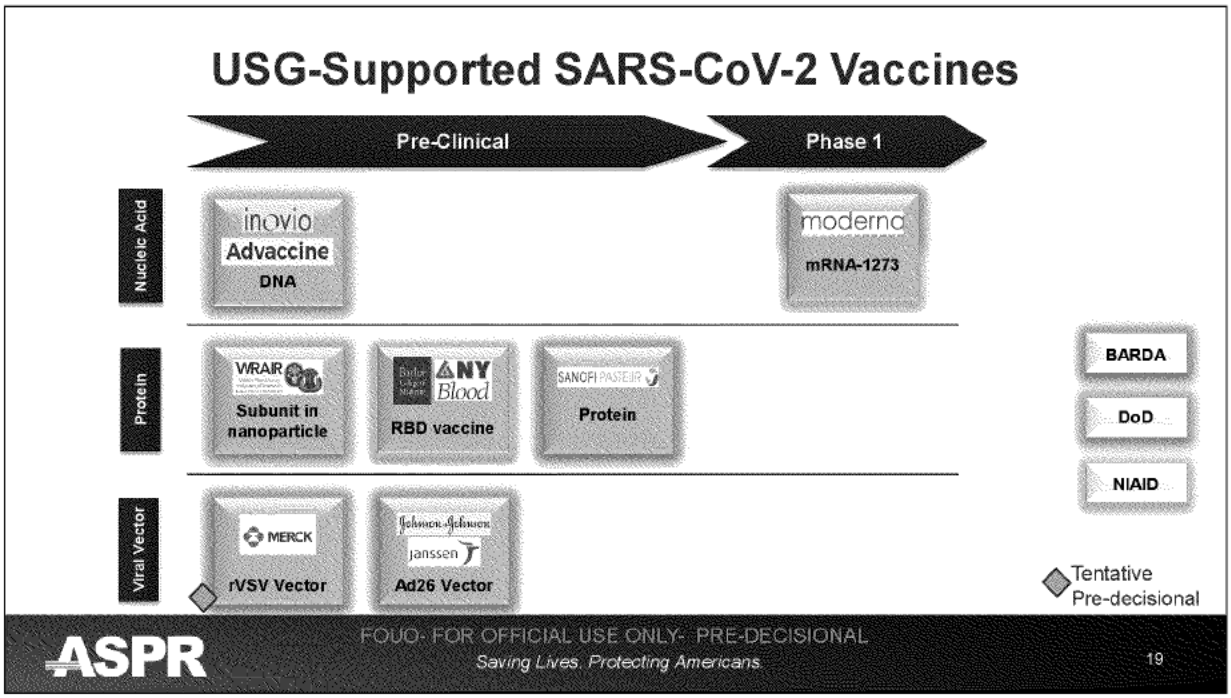
First to Clinic	Proven Platform	Production Scalability	Innovation
e.g., mRNA based vaccines that allow rapid early development	e.g., viral vectors with demonstrated safety and efficacy	e.g., Existing or readily amenable to large scale manufacturing, including experienced workforce	e.g., novel platforms, delivery approaches, or new thinking to transform the field

Leverage existing infrastructure for rapid MCM generation and production through partnerships (contracts and OTA) including other USG agencies



Pre-clinical
Hiltonol Poly-IC:LC
Lycorine;UKN;UKN; Shen 2019 JV 93:e00023-19
RTD-1 – Wohlford-Lenane 2009 JV 83:11385
UDA;Utah State University;Lectin – Kumaki 2011 Antiviral Res 90:22
SSYA10-001;University of Missouri;Helicase inhibitor;
Hiltonol Poly-IC:LC;Oncovir, Inc;Host; Kumaki 2017 Antiviral Res 139:1
RTD-1 peptide;The University of Iowa;UKN
Ribosomal inhibitors; Generic;Host

Phase 1
Camostat;UCSF;TMPRSS-2 inhibitor;Zhou 2015 Antiviral Res 116:76 (clinical use for chronic pancreatitis)
GS-5734/Remdesivir;Gilead; Sheahan 2017 Sci Transl Med. 9(396): doi:10.1126/scitranslmed.aal3653 (mouse SARS study), ClinicalTrials.gov Identifier: NCT03719586 (phase 2 Ebola study)
Sab-301;SAB Biotherapeutics;polyclonal anti MERS-CoV; Beigel 2018 Lancet Inf Dis 18:410
BCX4430;BioCryst;Nucleoside Inhibitor
EIDD-1931;DRIVE (Emory); Nucleoside Inhibitor
Phase 2/Observational
Ribavirin;UKN;Nucleoside Inhibitor
Convalescent plasma;Multiple Groups with capability; human polyclonal; Ko 2018 Antiviral Therapy doi: 10.3851/IMP3243
Corticosteroids;Generic;Host;: Arabi 2018 Am J Respir Crit Care Med. 197:757
IFN + Ribavirin;Generic;Combination antiviral and host; – Shalhoub 2015 J Antimicrob Chemother 70:2129
Lopinavir/Ritonavir + IFN-β1b; generic?;combination protease inhibitor and host; Arabi 2018 Trials. 19:81



Therapeutics
BARDA: Regeneron (Kevzara and TMPRSS2), (H)CQ, Genentech, Sab Biotherapeutics,
NIAID: Vir, DRIVE, Gilead
DoD: Therapeutic Interfering Parkticles, nCoV mRNA-mAbs, BioCryst

Vaccines
BARDA: Janssen, Sanofi Pasteur
NIAID and BARDA: Moderna
DoD: WRAIR nanoparticle, Inovio

Vaccine Approach

Accelerate Development

Rapid Vaccine Platform Approaches
- Nucleic Acid
- Vectors
- Recombinant protein

Repurpose Licensed Products
- Viral Vector
- Recombinant Protein

Parallel Activities
- Overlapping clinical trials
- Scale up in parallel with clinical development

Mitigate Risk

Multiple Platforms
- Address potential yield risks
- Address potential dose risk

Multiple Presentations (recombinant, vector, etc.)
- Disease enhancement mitigation
- Alternative routes of delivery

Redundancy
- Take multiple products through large scale clinical trials
- Multiple manufacturing facilities for each product

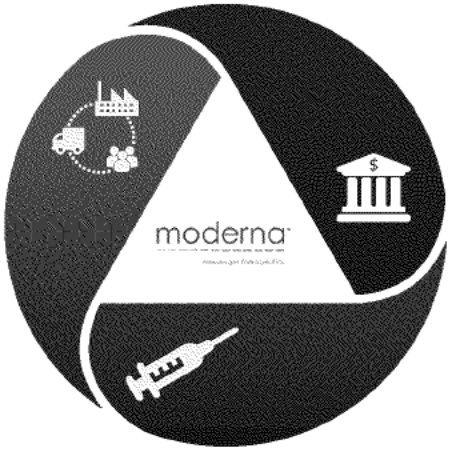
Domestic Manufacturing

Scale Up & Scale Out
- Validate large scale process (i.e. larger tanks)
- Technology transfer to more facilities
- Increase fill/finish capacity

Raw Materials Supply Chains
- Remove bottlenecks
- Establish stockpiles

Leverage Existing Facilities
- Facilities of large pharma partners
- CMOs

Moderna

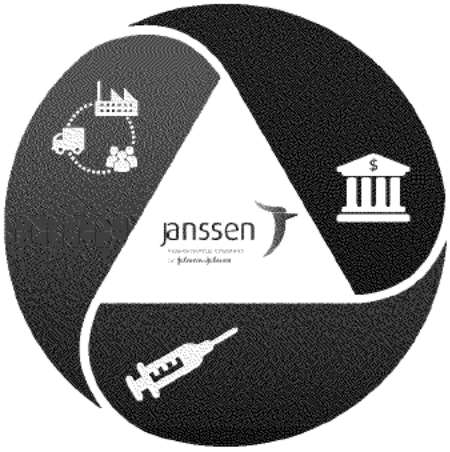


DEVELOPMENT
- First to clinic (1Q 2020)
- Phase 2 (2Q 2020)

RISK
- Unlicensed platform
- Scale-up constraints and limited experience
- Raw materials
- Required Dose

DOMESTIC MANUFACTURING
- Scale up (limited) and out
- Technology transfer to domestic facility – CIADM
- Secure supply chain

Janssen



DEVELOPMENT
- Parallel Work Streams
- Robust preclinical screening
- Phase 1 by 3Q2020

RISK
- Production yield
- Required Dose

DOMESTIC MANUFACTURING
- Technology transfer to domestic facility – CIADM
- Significant manufacturing experience mitigates risk

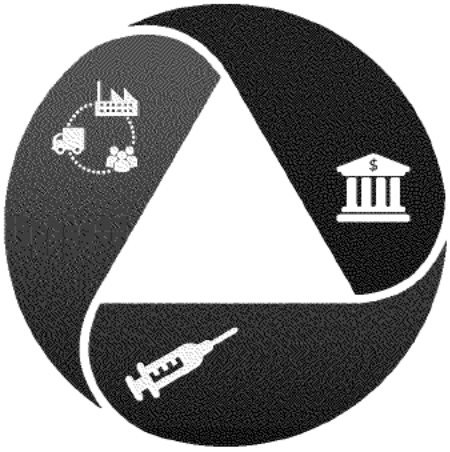
Sanofi Pasteur

DEVELOPMENT
- FDA-licensed vaccine platform
- Parallel Work Streams
- Phase 1 by 3Q2020

RISK
- Production yield
- Adjuvant likely required
- Capacity for COVID-19 vaccine shared with seasonal flu vaccine

DOMESTIC MANUFACTURING
- Licensed manufacturing facility available
- Production levels likely to be robust
- Experienced manufacturing team

Innovation



AREAS OF INTEREST

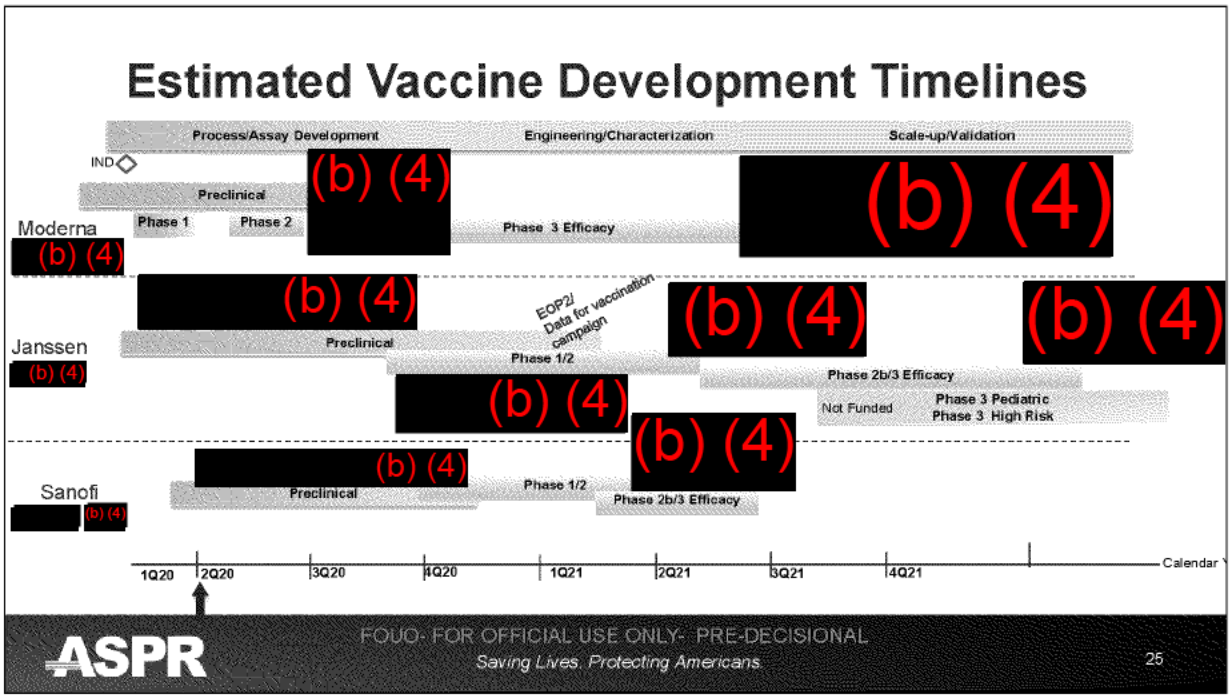
- Product yield enhancement
- Faster time to protection
- Operational improvements

IDENTIFICATION

- Handoff from other Government agencies
- High ranking from MCM review panels
- Leveraging opportunities (within and outside of Government (BMGF, etc))
- Assess timelines and domestic manufacturing capability

TARGETED STRATEGY

- Initial 'seed' funding to assess feasibility
- Flexible funding approaches
- Cost Share



To change the green/grey gradient:

1. click on the box you want to change
2. Go to the format tab
3. Click Shape FillGradientMore Gradientsmove the Gradient Stop “cursors” left or right as needed.

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/3/2020 1:58:07 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825[redacted](b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1[redacted](b) (6)]) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-[redacted](b) (6)]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; [redacted](b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-[redacted](b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344[redacted](b) (6)] Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Windom, Robert (OS/ASPR/IO) [Robert.Windom@hhs.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]

Subject: COVID-19 Advisory Panel
Location: WEBEx - 2027742300,,[redacted](b) (6)

Start: 4/5/2020 3:45:00 PM
End: 4/5/2020 4:45:00 PM
Show Time As: Busy

Recurrence: (none)

MEETING UPDATE as of April 5, 2020 at 8:28am - All please note this meeting time will shift to 3:45 to deconflict with the White House Task Force meeting starting at 5 pm Bob

- BARDA will present their portfolio and clear guidance

(Material/slide presentation forthcoming)

Hi Arwenthia Ford-Barnes,

Arwenthia Ford-Barnes updated this WebEx meeting for which you are an alternate host:

BARDA COVID-19 Advisory Panel Portfolio (on behalf of Dr. Robert Kadlec)
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
Start the meeting

When: Sunday, April 5, 2020, 4:00 pm (1 hr), Eastern Daylight Time (New York, GMT-04:00).

Access Information

Meeting Number:
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2027742300 (Meeting Server Main Number)

Access Code:
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Please excuse this mass email. I want to convey my greetings and best wishes from the Secretary who asked me to convene the Department's best people form CDC, NIH and FDA to periodically review, provide feedback and guidance to BARDA's COVID-19 MCM portfolio. I would expect this would be virtual and require read aheads providing detail of

prospective programs in vaccines, therapeutics, diagnostics and potential medical devices. I would anticipate a first meeting in April and quarterly after that.

The challenge is you are all extremely busy and the only way this works is provide materials well in advance and conduct a substantive meeting in 60-75 minutes. I have had the chance to speak to some but not all of you and I apologize if I haven yet personally reached out to you on this topic. Again I appreciate your potential interest and willingness to help support a national crisis and national investment in finding safe and effective countermeasures. Best Bob

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/6/2020 1:35:55 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1[redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-[redacted] (b) (6)]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-[redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344[redacted] (b) (6); Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Windom, Robert (OS/ASPR/IO) [Robert.Windom@hhs.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Kemp, Micha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37e66d7934924dbbb481f43a55477be7-HHS-Micha.K]; Lenihan, Keagan

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mark Hartell (b) (6)

Subject: #2 - COVID-19 Advisory Panel
Location: WEBEx - 2027742300,,(b) (6)

Start: 4/8/2020 5:15:00 PM
End: 4/8/2020 6:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Material/Slides will be provided by 12noon on Wednesday
(BARDA)

Please set up a call Wed evening with the same parties for a 75 minutes to focus on technical discussions on the vaccine candidates. More context to share. Best Bob

Hi Arwenthia Ford-Barnes,

You updated this WebEx meeting:

#2 COVID-19 Advisory Panel on behalf of Dr. Robert Kadlec
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
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When: Wednesday, April 8, 2020, 5:15 pm (1 hr 15 mins), Eastern Daylight Time (New York, GMT-04:00).

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Access Code:
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Subject: COVID-19 Advisory Panel
Location: WEBEx - 2027742300,,[redacted] (b) (6)

Start: 4/5/2020 4:00:00 PM
End: 4/5/2020 5:00:00 PM
Show Time As: Tentative

Recurrence: (none)

- BARDA will present their portfolio and clear guidance

(Material/slide presentation forthcoming)

Hi Arwenthia Ford-Barnes,

Arwenthia Ford-Barnes updated this WebEx meeting for which you are an alternate host:

BARDA COVID-19 Advisory Panel Portfolio (on behalf of Dr. Robert Kadlec)
Host: Arwenthia Ford-Barnes

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2027742300 (Meeting Server Main Number)

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From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/15/2020 5:18:34 PM
To: Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
CC: Tabak, Lawrence A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0037b2fbba164f33a24944311b80393e-HHS-Lawrenc]; Anderson, James M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ae7a825549453d8398a1d93d3d7d21-HHS-james.a]; Santangelo, George M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ec58f11ceaa4e5693d795f544aecb4d-HHS-george.]
Subject: Re: Curated portfolio of preprints and publications on COVID-19

Thanks, Francis. This is very helpful.
Best
Steve

From: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Date: April 15, 2020 at 4:50:26 PM EDT
To: Redfield, Robert R (CDC) <olx1@cdc.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tabak, Lawrence A (NIH) <lawrence.tabak@nih.gov>, Anderson, James M (NIH) <james.anderson2@nih.gov>, Santangelo, George M (NIH) <george.santangelo@nih.gov>
Subject: Curated portfolio of preprints and publications on COVID-19

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/3/2020 1:58:07 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; [redacted] (b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1[redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-[redacted] (b) (6) Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-[redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344-HHS-Vanessa]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Windom, Robert (OS/ASPR/IO) [Robert.Windom@hhs.gov]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]

Subject: COVID-19 Advisory Panel
Location: WEBEx - 2027742300,,[redacted] (b) (6)

Start: 4/5/2020 3:45:00 PM
End: 4/5/2020 4:45:00 PM
Show Time As: Tentative

Recurrence: (none)

MEETING UPDATE as of April 5, 2020 at 8:28am - All please note this meeting time will shift to 3:45 to deconflict with the White House Task Force meeting starting at 5 pm Bob

- BARDA will present their portfolio and clear guidance

(Material/slide presentation forthcoming)

Hi Arwenthia Ford-Barnes,

Arwenthia Ford-Barnes updated this WebEx meeting for which you are an alternate host:

BARDA COVID-19 Advisory Panel Portfolio (on behalf of Dr. Robert Kadlec)
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
Start the meeting

When: Sunday, April 5, 2020, 4:00 pm (1 hr), Eastern Daylight Time (New York, GMT-04:00).

Access Information

Meeting Number:
(b) (6)

Password:
(This meeting does not require a password.)

Host Key:
(b) (6) (Use this key during the meeting if you ever need to reclaim the host role.)

Audio Connection

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith [redacted]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly

Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/4/2020 8:27:17 AM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]

Subject: HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts

Attachments: COVID-19 Health Care System Resilience_Alignment of HHS Efforts_External_Agenda (2020-03-03) Final.docx; Key_Themes_Challenges_Gaps_(2020-03-03) FINALv2.docx; COVID-19 Health Care System Resilience_Alignment of HHS Efforts Meeting Deck_2020_03_03_vF.pptx

Location: Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement | Washington, DC 20515

Start: 3/4/2020 9:00:00 AM
End: 3/4/2020 10:15:00 AM
Show Time As: Tentative

Recurrence: (none)

REMINDER: It is requested that you attend in person.

Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement

If you are unable to do so, please participate via the dial-in information below:
Number: 202-774-2300
Access Code: (b) (6)

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to ASPR.HCSRTF@hhs.gov no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec
ASPR

POC:
Cicely L. Waters
Director, Office of External Affairs
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 C St, SW Washington, D.C. 20201

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U.S. Department of Health and Human Services
COVID-19 Health Care System Resilience: Alignment of HHS Efforts
Wednesday, March 4, 2020

O'Neill House Office Building
200 C St., SW, Washington, DC
ASPR Conference Center – Sub-Basement Level

Conference Line: 202-774-2300; 993 881 064# (access number)

Agenda

8:30 am – 9:00 am	**Registration/Sign In**
9:00 am – 9:05 pm	**Session Kick-Off** Facilitator Jack Herrmann Health Care System Resilience Task Force, ASPR
9:05 am – 9:15 am	**ASPR Opening Remarks** Kevin Yeskey, MD Principal Deputy Assistant Secretary, ASPR **CDC Opening Remarks** Nancy Messonnier, MD Director of National Center for Immunization and Respiratory Diseases, CDC
9:15 am – 10:00 am	**HHS Intra-Agency Discussion**
10:00 am – 10:10 am	**Summary & Next Steps**
10:10 am – 10:15 am	**Closing Remarks**

COVID-19 Health Care System Resilience: Alignment of HHS Efforts

Participant Response Analysis

Background: Responses submitted by OPDIV/STAFFDIVs by 3:00pm on March 3 informed the key themes, challenges, and gaps detailed below. Gaps were identified, in part, by comparing these responses to action items captured from the 2/19 Health Care Leadership Listening Session, other Requests for Information (RFI), and previous Health Care System Resilience Task Force meetings.

Key Themes of Activities:

- Dissemination of risk communication resources for at-risk populations including older adults and persons with disabilities (ACL, IHS)
- COVID-19 communication and provision of technical assistance with grantees, SLTT officials, and other health and human services stakeholders (HRSA, ACL, NHTSA, SAMHSA, IEA)
- Roll out of plans for agency telework policy (ASA, OMHA)
- Formation and coordination of HHS COVID-19 specific working groups across the agency (OASH, CMS, NIH, OCR with DHS and DOJ, ASPR, IHS, OCR, SAMHSA)

Key Challenges Identified:

- Consistent messaging across HHS, the interagency, and to the public, including culturally-relevant and linguistically-appropriate messages
- Availability of PPE and other supply chain concerns
- Continuity of HHS operations during COVID-19 response, given personnel deployment or employee absenteeism due to illness
- Ensuring workforce safety
- Shielding at-risk individuals from COVID-19 exposure
- Sourcing samples from recovering COVID-19 patients

Key Gaps in Activities:

- Dissemination of guidance (e.g., push methods to key audiences)
    - Clinical treatment guidance for health care providers
    - Workforce safety guidance
    - Infection control practice and community mitigation guidance for health care providers and health care workers, non-health care stakeholders and the general public
- Operational guidance on accessing federal stockpiles
- Operational guidance on regional sharing of people, supplies/equipment, space, information, and other assets for potential patient surge
- Concept of operations (CONOPS) for use of telemedicine
- Providing health care entities with reimbursement for uncompensated care for COVID-19 uninsured patients
- Reimbursement for costs associated with quarantine for Persons Under Investigation (PUI) and those asymptomatic or minimally-symptomatic COVID-19 patients at health care facilities
- Paid personal leave concerns for PUIs or COVID-19 patients
- Understanding the impact of health care worker furlough guidance
- Comprehensive coordination with private sector, specifically on:
    - Leveraging digital health
    - Implementing Crisis Standards of Care (CSC)
    - Innovative use of PPE
    - Developing training and exercises
    - Sharing information and situational awareness

COVID-19 Health Care System Resilience: Alignment of HHS Efforts

March 4, 2020

Objectives

1. Hone understanding of the **current landscape** of HHS' COVID-19 response
2. Confirm HHS components' **responsibilities, authorities**, etc.
3. Identify **potential gaps** in activities to **inform action plan**

Health Care System Resilience Task Force

The ASPR Health Care System Resilience Task Force facilitates **public-private sector collaboration** to support ongoing response and mitigation efforts nationwide. The Task Force works to establish and maintain a **common operating picture of health care system resilience**, providing **actionable decision support products** to federal leaders and private sector partners.

Task Force Members

HHS	Inter-Agency
Jack Herrmann, ***ASPR***	Jennifer Kishimori, ***DoD***
Anita Patel, ***CDC***	Francesca Music, ***DoD***
Skip Payne, ***CMS***	Paul Kim, ***VA***
Todd Lennon, ***HRSA***	Anthony MacIntyre, ***DHS FEMA***
Brooke Courtney, ***FDA***	Melissa Harvey, ***DHS CWMD***
	John Krohmer, ***DOT NHTSA***

CDC Opening Remarks

Inter-Agency Report-Outs

1. What is your **top priority** for this next week?
2. What are your biggest operational **challenges**?
3. What and/or **who do you need** to accomplish this priority?

Summary and Next Steps

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/3/2020 2:39:39 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]

Subject: HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts
Location: Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement | Washington, DC 20515

Start: 3/4/2020 9:00:00 AM
End: 3/4/2020 10:15:00 AM
Show Time As: Tentative

Recurrence: (none)

REMINDER: It is requested that you attend in person.
Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement

If you are unable to do so, please participate via the dial-in information below:
Number: 202-774-2300
Access Code: (b) (6)

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to ASPR.HCSRTF@hhs.gov no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec
ASPR

POC:
Cicely L. Waters
Director, Office of External Affairs
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 C St, SW Washington, D.C. 20201
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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/1/2020 8:11:14 AM
To: Debi Birx [Deborah.L.Birx@nsc.eop.gov]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Polowczyk, John P RADM USN JS J4 (USA) [john.p.polowczyk.mil@mail.mil]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]
Subject: Fwd: Ventilator Utilization Matrix for University of Washington Medical Center
Attachments: COVID-19 VENT Matrix.docx; Mount Sinai NIV Repurpose Modification Protocol - v1.01.pdf

Good morning,
I thought your teams would be interested from the front lines re: Utilization matrix for ventilators. This comes from the University of Washington. Dr. Josh Benditt went through this on Saturday's CMS doctors call. Not sure who would own this from a guidelines point of view but thought I would share.
Thanks
Steve

From: Czekai, Alina (CMS/CMMI) <Alina.Czekai@cms.hhs.gov>
Date: March 31, 2020 at 9:55:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: Ventilator Utilization Matrix for University of Washington Medical Center

Good evening,

Please see attached ventilator utilization matrix from Dr. Josh Benditt at the University of Washington Medical Center. This is the framework Dr. Benditt shared on Saturday's *Lessons from the Front Lines: COVID-19* call. Please let me know if you'd like me to facilitate any additional follow-up.

Best,
Alina
Alina M. Czekai, MPH
Office of the Administrator | Centers for Medicare and Medicaid Services
Phone: 410-913-6829

From: Joshua O. Benditt <benditt@uw.edu>
Sent: Tuesday, March 31, 2020 9:30 PM
To: Czekai, Alina (CMS/CMMI) <Alina.Czekai@cms.hhs.gov>
Subject: Ventilator Utilization Matrix for University of Washington Medical Center

Ms. Czekai,

Here is the our ventilator utilization matrix. I have included explanation and how we arrived at this.

I will forward other documents and procedures as we develop them for the surge that is upcoming.

Hope this is helpful.

Josh Benditt

Joshua O. Benditt MD, FCCP, RYT
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COVID-19 Ventilator Utilization Matrix for Invasive Ventilation
Prepared by Joshua O. Benditt MD and Federico Olivas BS, RRT

Background:

COVID-19 disease has the possibility of generating a surge of ICU patients requiring mechanical ventilation for ARDS. This surge could outstrip the current numbers of dedicated ICU ventilators to care for all intubated patients. Other ventilators that have not been used routinely in the ICU are available at the University of Washington Medical Center and at many hospitals around the country. However, the ability of these other devices to ventilate patients with ARDS for prolonged periods is not known. At the University of Washington Medical Center, we have devised COVID-19 Ventilator Utilization Matrix **to guide us if we were to reach a COVIV-19 respiratory failure case load that exceeds the number of dedicated ICU ventilators.** The tier numbering represents the order in which vents will be used once maximum capacity of dedicated ICU vents is reached.

The matrix was developed with the following issues in mind:

1. Has the invasive ventilator been used and found to be effective in treating intubated patients ?
2. Has the invasive ventilator been used and found to be effective in treating intubated patients with ARDS ?
3. Can the ventilator effectively filter exhaled gas through HEPA filters to avoid exposing healthcare workers to the SARS-Cov-2 virus aerosolized into the environment ?
4. Are the respiratory therapists currently trained to operate the ventilator? If not, can training be developed rapidly ?

Supporting action Items:

1. Inventory spreadsheet of all numbers of types of ventilator developed.
2. Spreadsheet of ongoing daily use of each type of ventilator developed.
3. Just in time video training for respiratory care practitioners for devices that are not frequently used in the ICU in development.
4. 1 page “cheat sheets” for infrequently used devices are in development.

Tier Level	Ventilator Type	Examples UWMC	Reliability for prolonged ARDS Treatment	Dual Limb Circuit (Filter exhaled gas)	COVID-Status	USE
1	Dedicated ICU	Servo-S, Servo-I	++++	Yes	+ and -	ARDS Patients
2	Transport	Revel, LTV	++	Yes	+ and -	Respiratory Failure Patients ARDS if necessary
3	Anesthesia/OR	Fabius	++	Yes	+ and -	Respiratory failure patients ARDS if necessary
4	Home Ventilators	Astral, Trilogy VOCSN	Unknown	Yes	- only	Respiratory failure patients ARDS if absolutely necessary
5	Hospital Noninvasive	V 60	Unknown	No	- only	Respiratory failure patients ARDS if absolutely necessary
6	Home Bilevel Devices*	Resmed ,Respironics	Unknown	Not currently	- only	Respiratory failure patients only

- See attached Mount Sinai Medical Center BiPAP Policy.

Mount Sinai

1 Gustave L. Levy Pl
New York, NY 10029
T 212-241-6500
mountsinai.org

Repurposing bi-level ventilators for use with intubated patients while minimizing risk to health care works during insufficient supply of conventional ventilation for patients with COVID-19

Version 1.01 [Mar 29 2020]

Mount Sinai Health System

Current Working Protocol – Subject to Revision

This current working protocol is subject to revision. It is expected this document will be updated and re- released as additional experience is accumulated.

Protocol developed by:

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Jing Wang, MD
Hooman Poor, MD
Brian Mayrsohn, MD
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This protocol is shared with our health care colleagues to increase knowledge about potential solutions to increase the capacity and access to mechanical ventilation during the COVID-19 crisis. Icahn School of Medicine does not warrant the contents or effectiveness of the protocol, and the use and implementation of this protocol should be first reviewed and evaluated with each hospital's medical staff.

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

The available supply of invasive mechanical ventilators is inadequate to fulfill the anticipated demand for these devices in a COVID-19 pandemic. These devices are required to support patients who present with acute hypoxemic respiratory failure secondary to viral infection. The recent development of approaches to modify invasive ventilators to support two patients may extend the supply of devices available to treat selected patients, yet it is unlikely to completely meet demand.

There is an abundant supply of non-invasive bi-level ventilators that are typically used to treat sleep disordered breathing. These devices can be modified to provide safe and monitored ventilation to patients with acute hypoxemic respiratory failure; the availability of these devices for repurposing is such that supply will be sufficient to better position hospitals to meet the anticipated ventilation device demand during the COVID-19 pandemic.

Experience accumulated from a long history of non-invasive ventilation by mask and anecdotal use of these systems with intubated patients suggests that these devices can provide adequate ventilation in a crisis. We have determined that bi-level ventilators intended for non-invasive use can deliver adequate ventilator pressures to support most patients with acute hypoxemic respiratory failure. Virus aerosolization and subsequent exposure of healthcare workers to the virus is a significant risk associated with use of non-invasive ventilators in the setting of COVID-19. This risk is mitigated by replacing the porous mask interface with a closed circuit delivering tidal volume via an endotracheal tube and by use of expiratory port filters. The ResMed VPAP ST device can be modified to add monitoring devices to allow for precise measurement and display of inspired oxygen concentration, tidal volume delivery, and expired carbon dioxide levels so that the adequacy of ventilation support can be assessed continuously from outside of the patient's room.

Taken together, we have developed a protocol that is capable of ventilating and monitoring patients with acute respiratory failure and mitigates the significant potential risks of exposure. This device has been tested in the Simulation HELPS Center at Mount Sinai, and the protocol has been validated in a clinical setting. We suggest that this system to repurpose noninvasive ventilators for invasive support of COVID-19 patients with acute hypoxemic respiratory failure can be utilized in the situation in which there is an insufficient supply of conventional respiratory ventilators.

2. KEY PROTOCOL RISKS & SAFETY FEATURES

The primary potential risks of the repurposed ResMED VPAP ST ventilator (VPAP ST) protocol are the risk of respiratory contamination from aerosolization, limitation of high oxygen delivery and delayed detection of hypoventilation and hyperventilation as described in Table 1.

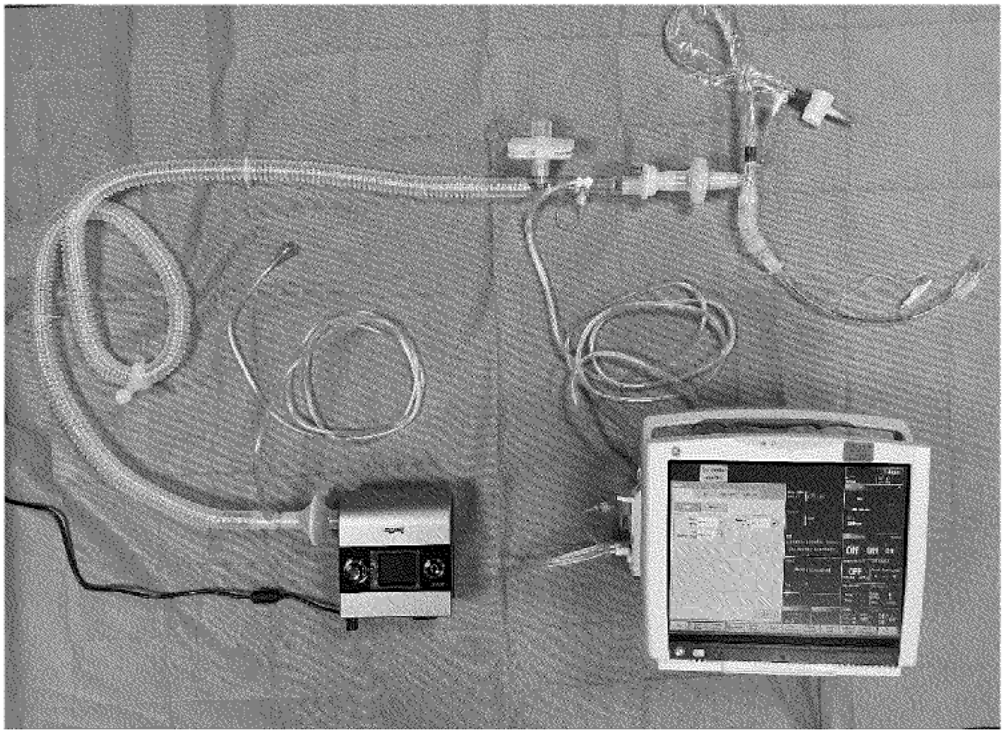
Table 1: Potential Risks and Mitigation Strategies

Risk	Risk Mitigation
Respiratory contamination from aerosolization, increasing risk to health care workers, if unmodified circuits are used.	Intubation with delivery of ventilation through an endotracheal tube is expected to reduce the amount of exhaled gas vented into the room other than by the ventilator circuit to near-zero. The ventilator circuit components and configuration are designed to capture and filter all gas exhaled by the patient with non-invasive single limb circuits.
Limitation of high O2 delivery imposed by the circuitry	Modifications of the circuit are intended to maximize inspired O2 levels if needed. Saturation monitoring will be used and patients will be switched to conventional respirators if needed (i.e. low O2 saturation despite maximal settings) if such ventilators are available.
Delayed detection of hypoventilation	Monitoring, including use of saturation monitoring and of capnography where available. Alarms to alert hospital personnel to circuit disconnection will be added as available, but are not a standard part of these devices.
Delayed detection of hyperventilation	Non-invasive ventilators are not likely to deliver sufficient ventilation to hyper ventilate at maximal settings. Monitoring of end-tidal CO2, if available, may suggest hyperventilation but should be confirmed by an ABG. Turning down the rate or level of ventilator support (IPAP-EPAP) will reduce minute ventilation.

3. EQUIPMENT & SUPPLIES

Specific equipment required may vary depending on supplies and equipment available.

1. ResMed VPAP ST (alternate bi-level devices would be acceptable)
2. Oxygen feed port (w/ 20' oxygen tubing, capped) [CareFusion 004204]
3. Second Oxygen port (w/ 20' oxygen tubing, capped) [CareFusion 004204]
4. Ventilation tubing
    a. Standard "leak-port" tubing (including from multiple manufacturers) is preferable
    b. Must include required exhalation ports (e.g. Fisher Paykel RT 219 or Phillips Respironics 1073228)
5. Inline heated humidifier (if available)
6. Exhalation port device with high resistance
    a. With attached filter (e.g. Filta-Guard 1944000)
7. Gas sampling adaptor for CO2 and flow monitoring (e.g. D-Lite Spirometry Kit 889560)
8. HME (inline moisture exchanger) if inline heated humidifier is unavailable (e.g. Covidien 353US908)
9. Endotracheal tube



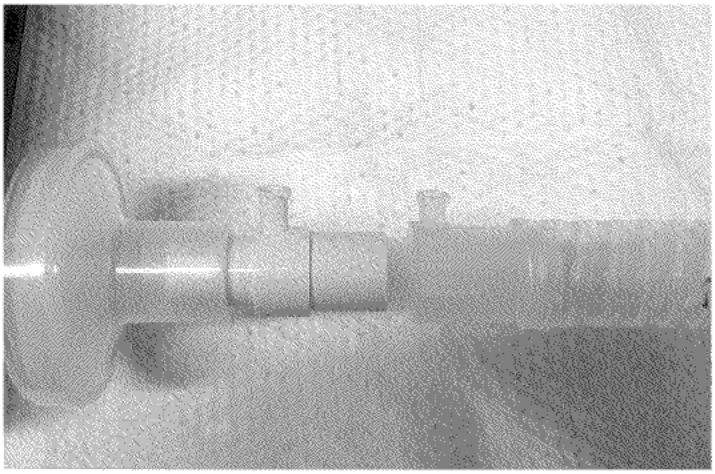
4. SETTING UP VPAP ST AND CIRCUIT

Step 1: Set up VPAP ST device by plugging it in, turning it on and holding down the "turn knob" and "double check" buttons together for 3 seconds to enter Clinical Mode

Step 2: Connect antimicrobial filter

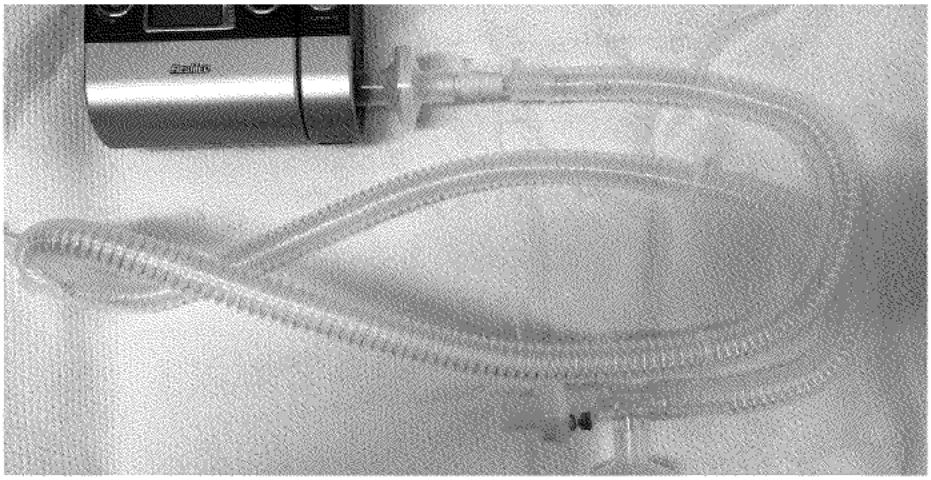
Steps 3 and 4: Connect BOTH inline O_2 feed ports (with 20' oxygen tubing) at VPAP ST outlet

- One tube is kept capped and in reserve for adding high O_2
- One tube is connected to 15 L/min source of O_2 (e.g. wall)



Step 5: Connect VPAP ST tubing circuit

- Preferably standard circuit with exhalation port (e.g. Fisher Paykel RT 219 or Phillips 1065832)
    - If needed any standard ventilator tubing can be used, but an exhalation port device must be added if it is not included
- Circuit MUST include exhalation "leak-port"
    - If using standard respiratory tubing, can add standalone exhalation port (e.g. Fisher Paykel RT017 or Philips 1065775)

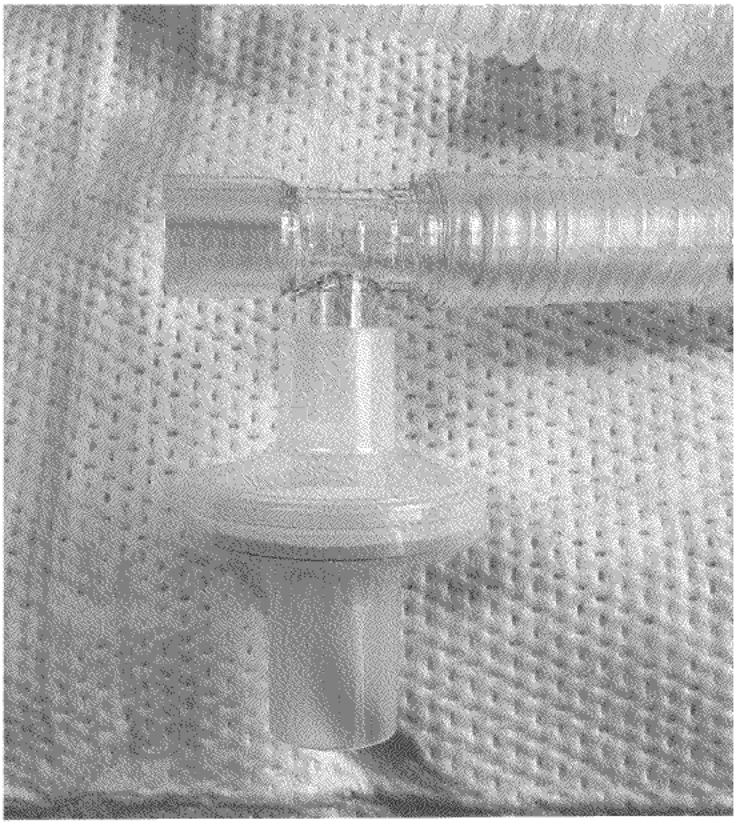


Step 6 (optional): When available, add inline heated humidifier if available (e.g. Fisher Paykel stand-alone humidifier)

Not pictured

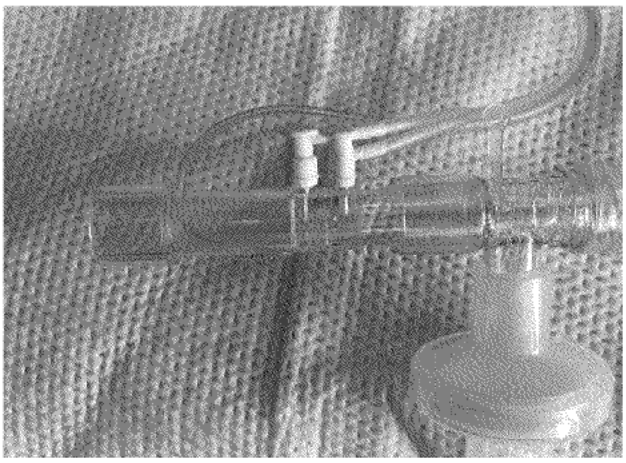
Step 7: Verify that the exhalation port device with high resistance is present and can accept a viral filter

- This should be near the patient, e.g. at end of tubing.
- Attach viral filter after exhalation port (so it can be changed when wet or clogged)

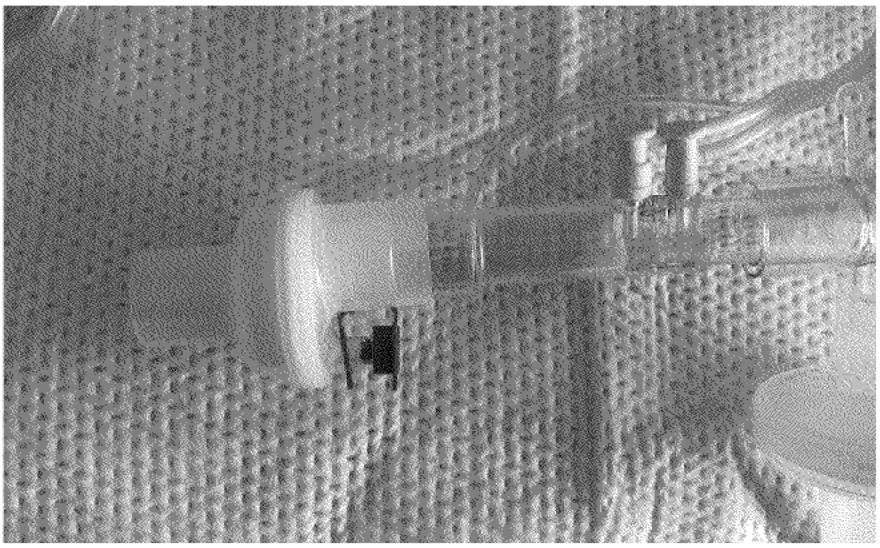


Step 8: If available, attach gas sampling adaptor for CO_2 and flow monitoring

- This is for monitoring only and does not affect system performance



Step 9: Use inline heat and moisture exchanger **(HME) if heated humidification via reservoir is unavailable**



Step 10: Set to Bilevel ST mode. Suggested default settings at a glance (refer to Step 12 for details):

- ST mode
- Smart Start OFF
- IPAP 25
- EPAP 15
- Backup Rate 20 or 5 less than patient's spontaneous rate.
- Set TiMax to 1.2 seconds and TiMin to 0.6 seconds
    - These may need to be adjusted if patient RR is greater than Backup Rate (see Clinician Guide)
- Rise time: min

SAFETY CHECK: If available, connect a "test lung" to the end of circuit and verify that it inflates when setting VPAP ST to IPAP 25, EPAP 15, Resp Rate 25.

Step 11: Attach setup above to ET tube and patient

- The cuff on ET tube should be inflated.

Step 12: Initiate ventilation

1. Set Mode: ST (do not use CPAP, S or T modes)
2. Set IPAP: Start at 25 (likely will need max = 25 cmH20)
3. EPAP 15
    a. Do not increase EPAP if ventilation is needed, can use high EPAP if PEEP (oxygenation) alone is needed
    b. NOTE: Increasing EPAP alone without increasing IPAP will reduce ventilation
4. Check Tidal Volume (TV) read out (on VPAP ST screen or gas sampling/flow monitor if available)
    a. Calculate what TV is 6 cc/kg (IBW) for patient (usually 300-400 cc)
    b. If TV is over goal, IPAP can be reduced (or EPAP raised if additional support for oxygenation is needed). If TV is under goal, IPAP should be increased (if not already at maximum of 25 cmH20). Refer to clinical guide for details.
5. Set Respiratory Rate:
    a. Initially 5 less than patient breathing (no less than 15, can be as high as 25-30, but level of FiO_2 attained may worsen with increasing rates)
    b. Check FiO_2 via gas sampling/flow monitor if available

*****If the patient's ventilation needs cannot be met by the above IPAP/EPAP and RR settings, an alternate ventilator should be considered *****

1. Set TiMax to 1.2 seconds and TiMin to 0.6 seconds
2. Set Rise Time: Min
3. Set Trigger: Low
4. Set Cycle: Low

***IMPORTANT: Disconnecting the VPAP ST circuit is an **aerosol-generating procedure.** Anyone present for this procedure must wear appropriate PPE, including eye protection and an N95 or equivalent respirator.

5. PATIENT SELECTION

This mode of ventilation is expected to be similar to pressure control ventilation. Patients who meet the following criteria will be eligible for treatment with this mode of ventilation:

1. Patients with milder respiratory failure who still need ventilator support.

   OR

2. All patients if there is no other ventilator available. It is likely to work best in those with higher lung compliance (appears to be relatively frequent in many COVID-19 patients).

   OR

3. Patients being weaned from mechanical ventilation as they stabilize and improve may benefit equally from this ventilator and thus free up more advanced ventilators.

NOTE:

- Patients with need for high levels of FiO_2 may be eligible, but second O2 input port or further modifications of the leak circuit will be required. Simplest modification to increase delivered FIO2 is to utilize the second oxygen bleed in (see circuit) with an additional 15 L/min O2 (up to 30 L/min O_2 total for two ports). In order to prevent backup of oxygen into the VPAP ST blower:

  Do not increase bleed-in of oxygen to a level that produces FiO2 > 95% at the endotracheal tube.

- Because of dyspnea and risk of patient self extubation, it is expected many patients may require sedation or even paralysis. While this likely will improve efficacy of mechanical ventilation, it carries an added risk in these patients due to the lack of alarms and backups available with these ventilators. Due to the lack of alternative, this is a risk that may be unavoidable and must be mitigated by minimizing sedation and paralysis, and maximizing supervision by staff of the patient. However, if an alarm for disconnect can be provided (eg via a separate pressure monitor, or using the existing monitoring port for volume, Co2, etc and existing software connections) this alarm is highly desirable and should be set.

6. MONITORING & SUPPORT DURING USE OF VPAP ST

The VPAP ST was not intended to be a life support device and thus has no safety alarms. Because of this, close observation of the patient is critical and there should be added caution with sedation and neuromuscular blockade

Due to the highly contagious nature of COVID-19 and the risk of infection with close contact, it is unlikely there will be a healthcare worker in the room to monitor the patient. To mitigate risk of infection of healthcare workers, these patients will be monitored from outside the room whenever possible after initial stabilization post-intubation using telemetry (where available). Frequent spot checks will be performed if telemetry equipment is limited. Spot checks should include

1. Monitoring of O_2 sat via continuous pulse-oximetry
2. End tidal CO_2 and respiratory rate (low or high), when available
3. Tidal volume, FiO2 and flow monitoring via telemetry equipped with spirometry module (e.g. GE Carescape monitor with D-fend Pro + spirometry module)
    a. **If this module is used, alarms can be introduced**

7. CARING FOR PATIENTS USING VPAP ST

Managing Shift Changes

Each time there is a shift change for staff caring for patients being treated with a VPAP ST, outgoing and incoming staff should review key safety elements, including the following:

- Location of this protocol
    - Must be available at the patient's bedside at all times
- State of sedation and paralysis of the patients
    - If there is no spontaneous respiratory effort, added supervision is needed.
- Circuit configuration, including how to reconnect if ever dislodged or disconnected.
- Whether or not there is availability of acute airway and respiratory backup support devices, including location of bag valve mask and rescue ventilator nearby (if available)
- Inspection of expiratory filter and replacement if wet (this will increase resistance and reduce CO_2 venting)

Key Considerations to Take into Account Before Making Changes to Settings:

- Higher pressures (both IPAP and EPAP) will increase the leak through the expiratory port. This may lower the FiO_2 due to added entrainment of room air.
    - Increase bleed into the circuit of O_2 from second port if this occurs (if not already at max).
    - Check FiO2 with gas sampling/flow monitor, if available.
        - If FiO_2 is already at 100% and saturations are inadequate, escalation of ventilator strategy may be needed.
        - Further increase in FiO_2 requires modification of circuit to reduce leak flow.
- IF THE EXHALATION LEAK PORT IS MODIFIED, pressures in the circuit to below an average pressure of 10-15 may drop the leak flow below 15 L/min (minimum to prevent CO_2 rebreathing) and cause hypercapnia.
    - This will not happen with the commercially available unmodified expiratory port unless there is blockage of the port or any attached filter as by secretions. Promptly examine port and filter for patency if patient experiences increasing hypercapnia.

If possible, a standard ventilator should be available for use in case the patient cannot be maintained on the repurposed VPAP ST (bilevel). It is understood, however, that a standard ventilator is not likely to be present as the primary purpose of this protocol is to deal with limited availability of standard ventilators.

8. ADMINISTRATIVE AND ETHICAL CONSIDERATIONS

Hospital administration must approve this protocol before use, acknowledging the unique ethical considerations.

This protocol is only appropriate for consideration when (i) crisis standards have been instituted, (ii) there are not enough ventilators to meet demand for ventilation of intubated patients with a reasonable probability that intubation/ventilation will be lifesaving.

Ethically, it must be recognized that the conversion of ventilators meant for non-invasive ventilation to use with intubated patients is not the usual standard of care, but in the setting of a mass crisis, such as the COVID19 pandemic, the number of potentially rescuable patients may exceed the number of ventilators to support them. Initial experience with the repurposed non-invasive ventilators indicates that the proposed use of these devices as outlined above offers the best chance at saving the most lives in the current pandemic climate. The use of the repurposed non-invasive ventilators should be discontinued as soon as a sufficient supply of ventilators becomes available.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 6:50:15 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: THe S2 called me

Bob,
It's really helpful for cycling of respirators which is what the current EUA is about. My electrons, do you mean background info?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 29, 2020 at 9:31:34 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: THe S2 called me

Steve & Keagan he told me about the Battelle N-95 recycling system Do you have any electrons on that? Sounds exciting. Thank you Bob

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/25/2020 7:11:10 PM
To: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; (b) (6) (OS/IOS) (b) (6)@HHS.GOV]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
Subject: Re: Georgia lifts restrictions on two medical device sterilizing plants

Well done, Mr. Secretary.

From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Date: March 25, 2020 at 7:09:18 PM EDT
To: AMA2 (OS/IOS) <AMA2@HHS.GOV>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Stecker, Judy (OS) <Judy.Stecker@hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>, Charrow, Robert (OS) <Robert.Charrow@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Subject: Fwd: Georgia lifts restrictions on two medical device sterilizing plants

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From: POLITICO Pro <politicoemail@politicopro.com>
Sent: Wednesday, March 25, 2020 6:48 PM
To: Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>
Subject: Georgia lifts restrictions on two medical device sterilizing plants

Georgia lifts restrictions on two medical device sterilizing plants

By Annie Snider

03/25/2020 06:47 PM EDT

Georgia regulators have agreed to temporarily lift environmental restrictions on two plants that sterilize medical devices in order to increase supplies of protective gear and other products during the coronavirus pandemic.

The two Becton Dickinson plants have been operating at reduced capacity since the fall due to concerns about emissions of a cancer-causing gas used in the sterilization process. Georgia regulators and the company agreed to the changes in an amended consent order approved by a state court Wednesday. A third plant in the state, owned by the company Sterigenics, remains shuttered.

"These changes are necessary to ensure hospitals have enough sterilized medical devices available to treat the

influx of COVID-19 patients," the Georgia Environmental Protection Department said in a statement. It said the equipment of most concern that is sterilized at the plants include Foley catheter procedural trays, Foley catheters, PICC line catheters, and acute dialysis catheters.

The restrictions will go back into effect 14 days after Gov. Brian Kemp lifts the public health emergency declaration he issued in response to the outbreak.

The move comes after FDA Commissioner Stephen Hahn wrote Kemp last week raising concern that the recent closure of commercial sterilizers in the state had impacted the availability of personal protective gear and urging his assistance in getting them back online.

He specifically cited the Sterigenics plant near Atlanta, which has been offline since August in order to install new pollution control equipment.

In a statement on its website, Sterigenics said that more than 1 million protective gowns that were previously sterilized at its Atlanta plant are awaiting sterilization, and that the plant is also approved to sterilize swabs for one of the two FDA-approved coronavirus test kits.

"Sterigenics and other sterilization industry facilities are already safely operating at near full capacity. The only way for Sterigenics to sterilize more lifesaving equipment is to reopen the Atlanta facility," the company said.

Cobb County, Ga., commissioners on Monday allowed the company to proceed with previously-delayed air testing. In a statement, the commissioners said the testing would take place "in the next few days" and the results would then be sent to state environmental regulators. They also said they are awaiting the results of a third-party investigation into the plant's operation and fire code compliance.

"We recognize that Sterigenics could assist the community in combating COVID 19," County Manager Rob Hosack said in the statement. "However, several critical steps must be completed before Sterigenics can safely reopen and comply with fire safety codes and other county ordinances as has been shared with Sterigenics."

Operations at the Georgia plants, as well as sterilization plants in Illinois and Michigan, were disrupted following public outcry over emissions of ethylene oxide, a colorless, odorless gas that is linked with breast cancer, leukemia and other cancers. It has been used for decades to sterilize medical devices, but in 2014 the Environmental Protection Agency found that it posed health risks at far lower levels of exposure than previously thought — a conclusion that industry disputes.

EPA is currently working on updating its emissions rules for sterilizers, although that process is behind schedule.

EPA Administrator Andrew Wheeler on Wednesday endorsed the move by Georgia to reopen plants.

"While we must take into account the risks from emissions of ethylene oxide ... it's important to bear in mind those risks are linked to exposure over an entire lifetime, however COVID-19 poses an immediate threat to our nation during this crisis," Wheeler said in a statement.

David Lim contributed to this report.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/03/georgia-lifts-restrictions-on-two-medical-device-sterilizing-plants-1902743

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/22/2020 3:27:34 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Used PPE Sterilization - Response to your request plus additional detail
Attachments: 3rd letter to nelson for steve hahn.docx; Sterigenics intro and proposal.docx

Jeff,
Have we received any applications on this? Bob and Paul, is this something that HHS would respond to?
Thanks
Steve

From: (b) (6) >
Date: March 22, 2020 at 3:22:30 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Used PPE Sterilization - Response to your request plus additional detail

Hello Dr. Hahn,

Thank you for your response and enthusiasm regarding our efforts. It is exciting to have you as an advocate and may I say sponsor for this effort. Attached is a complete listing of items which we are addressing with Sterigenics, soon to be a partner in this effort to sterilize PPE for reuse and relieve some of the shortfall in available protective equipment for our "brave and dedicated front line personnel". This document along with the document texted to you should be useful in informing any and all, engaged, or to be engaged, parties. I can resend the document texted to you should you have use for it. If there is any other information which you need from us please advise. Angelo and I have 4 oars in the water (2 each).

Sincere Regards,

Nelson and Angelo

3/22/20

Dr. Hahn, this is some background information and a progress report of our current actions regarding the engagement of Sterigenics in pursuit of our goal to sterilize PPE for one or more reuses. This information is probably suitable for hand off to whomever, if accompanied by the introductory document which was texted to you. If you like I can forward that preliminary document to anyone of your choosing.

Sterigenics is a company in the business of utilizing Cobalt 60 gamma, electron irradiation and ethylene oxide to decontaminate PPE for re-use. The company has multiple sites in the United States and has excess capacity. We have had numerous discussions and exchanges of information with Sterigenics as we pursued interest in marshalling an effort to sterilize PPE for reuse. They are anxious to join in the effort.

The following has been addressed to Sterigenics re their objectives and expectations:

- is this a "Civic Duty response?"

- is this a full-on profit motive pursuit of business response, (which may complicate matters far as expeditiously handling is concerned, except for Cuomo's approach), or

- is this a Civic Duty - Break Even response

- is this a Civic Duty - Break Even + some small %

In that regard Sterigenics has addressed the following issues internally:

- Meetings with their business organization to clarify and confirm issues related to engagement however "preliminarily":

- Sterigenics has excess capacity available for immediate allocation to civic needs - Civic Duty Response

- They have a substantial volume of contract business which would require cost coverage for lost business or conscription by the government, i.e. **it would/could have to be preempted (Trump's War Powers Act)** however some of this business might not be suitable for **preemption** as it might be related to other critical demand items

- In some cases Sterigenics might wish seek direct cost recovery

Discussions with Sterigenics identified the following:

- Expeditious processing will require:

  ** separating materials into like groups or "classes" would be desirable e.g., class 1: of head covers, foot covers, gowns, jump suits; class 2: masks; class 3: gloves; class 4: face

shields. Sub groupings might become necessary as a function of different materials; all of which must be sorted according to class and sub class. *Sterigencis is currently discussing the topic of reprocessing of masks with several companies who routinely handle medical device reprocessing. They may have existing processes to be able to handle the items listed in this bullet.*

** bags gathered from hospitals would need to be "boxed" to make compatible with their processing equipment

** determination of processing times will require an understanding of volumes and classes of materials and sterilization means, e.g. Gamma, EO, e-beam, etc.

** we would/will need to define a co-ordinated process for implemented and scaled operation. ***This process would not only need to include the initial reprocessing but also have a method of tracking the number of times a mask had been reprocessed as any degradation will increase with additional reprocesses.***

** will need estimate of quantities to be processed by each sterilization means

- Sterigenics will/could evaluate and recommend sterilization means e.g. Gamma Irradiation, e-beam, EO, etc. in co-ordination with task group(?) as a function of classes and sub-classes; different classes and sub classes will potentially require different sterilization means

  - Different sterilization processes are not all available at any one site but mostly at different sites, therefore co-ordinated logistics will be involved. ***Sterigenics is already handling this in a centralized fashion for newly manufactured PPE that is being made for use during this crisis.***

  - Sterigenics agreed to the necessity of a test model for the scaled-up operation addressing steps in the process and divisions of responsibilities; this can/will be used to establish time frames and production schedules

- Sterigenics would like to see a task group, such as from the CDC, NIH, ***FDA,*** Homeland Security, HHS, "with a coordinator," established; ***Sterigenics is also looking to recruit companies other from industry who can provide input on this process for a task group as well.*** Sterigenics would like for us to continue our involvement for the time being, until the government agency task group becomes functional as they do not have an expeditious pipeline to information and for co-ordination

- Sterigenics will need to present a plan of action "and" proof of concept proposal. Where proof of concept means that Sterigenics must test the process on x number of masks: **of different design** (there must be more than one, but how many?), **different filter materials** (if there is more than one), and **different manufacturers** (if this is relevant for some reason, then there must be many!) I don't think that Sterigenics can do this without some interaction and reasonable guidance

** Sterigenics and affiliates already do similar processing, just not on "used or after use

contamination". ***Sterigenics also has a testing laboratory affiliate with expertise in cleaning and disinfection as well as mask barrier testing.***

** some centralized agency will need to provide an estimate of quantities to be processed by each sterilization means following the prof of concept tests

- Sterigenics will/could evaluate and recommend sterilization means e.g. Gamma Irradiation, e-beam, EO, etc. in co-ordination with task group(?) as a function of classes and sub-classes; different classes and sub classes will potentially require different sterilization means

- He agreed to the necessity of a test model for the scaled-up operation addressing steps in the process and divisions of responsibilities; this can/will be used to establish time frames and production schedules

- Sterigenics will describe their facilities process for each type of irradiation and sterilization

- Sterigenics needs to know the sterilization standards, for example:

**zero detectable pathogens

**some significantly reduced level (but who determines the level and sets the standard?)

- Sterigenics needs for someone to determine how testing for contamination post processing will be carried out and certified, and by whom?

- What are the Current Standards for PPE respirator performance testing re fit (critical) and penetration (very critical)

- What **will be** the Performance Standard post sterilization
** current Standard

** some form of Relaxed Standards

Note: Sterigenics has some information regarding some materials degradation resulting from gamma exposure

- Sterigenics needs some guidance regarding the prescribed irradiation dose for deactivating the Covid-19, or must this be derived by testing ... prescribed is simpler, but who commits to setting this standard, and is it really a known quantity? Probably not in this case! Sterigenics would like to collaborate on Governments scientifically recommended irradiation level(s) for deactivation levels required

- Sterigenics is pursuing any and all Chinese interaction related data:

** Sterigenics is seeking information from China related affiliates, but does not currently have full details; he is aware that e-beam was ***tested*** on some items (?)

To Whom It May Concern:

The letter below defines an exciting opportunity for an industry and government collaboration, marshalled to meet the current shortage of essential equipment in the COVID-19 pandemic. Repurposing the M3 8511 N95 masks provides a timely and cost-effective means to meet NYS's need, plus the needs of others for this essential piece of equipment that is in short supply.

This letter addresses and proposes the use of high intensity GAMMA IRRADIATION STERILIZATION of PPE and other alternative means for large scale/volume sterilizations, any and all of which if/when implemented would greatly help protect our public health professionals & provide NYS a timely, innovative response to the COVID-19 assault on medical resources and supplies.

Subject: Radiation sterilization of PPE (Personal Protection Equipment) for reuse.

Introduction, Summary Proposal and Offering of Services

After discussion with Nelson English and Dr. Angelo Russo who have worked throughout the day to effect a rapid response from Vice President of Global Quality Assurance for the principal in this proposal Sterigenics Corporation, it was decided that a preliminary time line needed to be added, to the initial proposal; following this *Introduction* is a Statement of a Preliminary Timeline, Background, Concept and Proposal from the Sterigenics Corporation affiliated with Nordion Inc and Nelson Labs Inc. Mr. Dement responded expeditiously.

The proposal provides a strategy to employ a method or methods to immediately augment availability of sterilized personal protection equipment, PPE, needed by health care workers providing care of patients and monitoring of the Covid-19 pandemic. Currently under the best circumstance used PPE is being discarded. But because of PPE shortages health care workers are resorting to use of contaminated PPE. Such re-use of contaminated PPE places the health care worker and patients at an increased risk of contracting Covid-19 which will result in further health care shortages. Right now, as I write to you, there is ever increasing shortages of PPE in the current Covid-19 pandemic 'hotspots' in the USA. Soon, shortages will become commonplace throughout the USA

New York Governor, Andrew Cuomo, amongst many others, has been desperately seeking to protect health care workers by means of acquiring more PPE. Increased output of new and replacement PPE by the manufacturing industry "**may be on the horizon**", but currently industrial manufacturing of needed PPE is badly lagging behind needs and apparently struggling to respond to overwhelming demands. When and how many health care workers will be at increased risk until such a response can be made, at present, unknown. There are no firm timelines/deadlines known as to when de novo manufacturing of **fully compliant mask**s will meet the current and expected increasing need. So, a strategy is needed to "fill in the gap" until adequate quantities of new PPE can be manufactured and made available

Sterigenics is a world-wide company with sites in the USA positioned to offer "fill in the gap" technology by sterilizing PPE employing high intensity cobalt irradiation sources and to augment with other means. In the first case the destructive gamma radiation emanating from radioactive cobalt can be used to deactivate the coronavirus in/on contaminated PPE. This can be performed in immediately available facilities. Collaterally any other contaminating biologic forms will be deactivated. The PPE exiting the facility, after having been irradiated will be sterile and ready for packaging and reuse.

When you read the following document from Sterigenics you will note there are plans already underway in Europe to proceed as early as tomorrow in testing the efficacy of the method. If employed by Governor Cuomo the aim is that the US Government at large, coordinated originally through Governor Cuomo office will have a ready method to improve the safety of health care workers through increased availability of safe PPE. Since Governor Cuomo is a no-nonsense administrator who is looking for immediate implementation techniques to alleviate PPE shortages, where possible, the increasing stress being caused by the Covid-19 pandemic, I am asking for your help in facilitating this proposal to the Governor and beyond. This proposal should and must be seriously considered. Following is an email correspondence with Aaron DeMent the Vice President of Global Quality Assurance of Sterigenics, the entity responsible for this proposal.

Nelson English and Dr. Angelo Russo

Sterilization - Reprocessing of Masks and other PPE items relating to COVID-19 Treatment Interventions

Per the request of Nelson English, I have reformatted some the elements to match how the qualification process works. I am collaborating with people on our team to try to determine estimated time frames for the parts we would have more control over from a technical perspective. See my thoughts following:

Engagement Process Timeline (preliminary):

- Initial contact with "users" (represented by regulators in this case) and understand your needs
- Internal discussion – Sterigenics / Nelson reviewing needs
- Response to "users"
- Method / Approach Development – In progress
- Protocol development
- Processing
    - Radiation
        - Expedited shipping 1 day
        - Expedited processing 1 day
        - Return shipping to testing lab 1 day
    - Ethylene Oxide
        - Expedited shipping 1 day
        - Expedited processing 4 days – 1 day precon, 1 day processing, 2 days aeration
        - Return shipping to testing lab 1 day
- Testing
- Final Report
- Regulatory Approval

Updated with a "current actions" section at the bottom.

Thank you for taking the time to speak with me about reprocessing and sterilization of masks and/or PPE related to COVID-19 this afternoon. As I mentioned on the call today, globally we have received a large number of requests regarding reprocessing of PPE in the past 48 hours. As the majority of the initial requests were coming from Europe we have spent much of our time working a response to this crisis with authorities in countries like Belgium and Italy.

From our company's perspective, we can play two significant roles in the response to this crisis.

- Sterilization: Our Sterigenics business unit has 21 gamma irradiation, 16 ethylene oxide (EO) and 5 electron beam sterilization facilities. Of these 14 gamma, 8 EO and 2 E-Beam facilities are in the US. We have committed that we will divert capacity of these facilities to products related to the COVID-19 crisis, or to other critical care products as needed during this time. The Sterigenics website is [HYPERLINK "http://www.sterigenics.com/" \t "_blank"].
- Laboratory and Scientific Expertise: Our Nelson Laboratories business unit houses expertise in both the testing of masks and other PPE for barrier properties as well as a strong understanding of device cleaning and reprocessing. I have attached a white paper they have developed regarding their capabilities on Coronavirus. You can find out more about Nelson Labs in general at [HYPERLINK "http://www.nelsonlabs.com/" \t "_blank"].

With respect to what our company has been doing in relation to the Coronavirus the past few days, we are starting to receive a lot of requests to reprocess mouth masks and other PPE due to significant shortages. Many of these products were designed as single use and reprocessing was not conceived. We are working with the Belgian government (AFMPS) to organize a task force to try to develop an effective reprocessing method. Given the global nature of our business, we would really like to have more global participation so we can have a consistently effective process we can use anywhere.

Things we are currently thinking about:

- We would like to get a group of key stakeholders to try to come up with some consensus on how to reprocess PPE if possible. Our thoughts are stakeholders would include:
o Users of the PPE
o Original manufacturers
o Re-processors

o Sterilization providers
o Testing Laboratories
o Regulators
- Goals of things we are interested in understanding and have a consensus on include:
o Cleaning post use: Who is responsible and how? Care has to be taken on this step not to damage the barrier on the mask or PPE, so cleaning methods need to be appropriate. Things like an alcohol spray may be applicable. Our Nelson Labs group is looking into this in detail at the moment.
o Packaging method: The more consistent the packaging method is, the easier it is to come up with a standard sterilization process. The packaging needs to be compatible with the sterilization method.
o Processing goal: Is there going to be a sterile claim, or will it simply be some level of microbial and/or viral reduction? We are aware that gamma irradiation can inactivate the coronavirus but with the proper cleaning method, or a waiting period before reprocessing, it may not be necessary to aim for viral deactivation. In a case like this, Ethylene Oxide (commonly used for PPE sterilization) may be a more gentle method.
o Functionality: What tests are required to guarantee functionality (see the attached white paper from Nelson Labs)? How many reprocesses would be allowed? This is a key point we need to have care with, as the masks will suffer degradation over multiple processes. A tracking method may be critical.
- Current Activities:
o Testing: We are currently working with the Health Authority of the Tuscany region of Italy to test a variety of products after a 25 kGy gamma irradiation process. We expect to receive the product on Monday. We have not seen the protocol for this test and are trying to get more information in addition to describing to them some of our thoughts as noted above
o Collaboration: We are working with the Belgian authority (AFMPS) to develop a task force of PPE reprocessing as noted above
o Sterigencis has set up a single point of contact from a commercial standpoint to ensure that we can expedite and COVID-19 related products anywhere in the globe. We are currently developing a tracking list of every such product to the best of our knowledge.
o We are working with a re-processor in the US to process PPE product through EO. They are going through internal testing as we speak in an effort to produce a 510k submission package for reprocessing of PPE. For other non-510k type products (such as the N95 mask) they are testing for effectiveness in a similar manner.
o Our laboratory group is working on developing a proposed cleaning and testing approach.

We look forward to speaking with you more. We are clearly going to face a big need.

Kind Regards,

Aaron DeMent
Vice President, Global Quality Assurance

To the Addressee: you should feel free to by-pass me and reach out directly to Aaron Dement, Vice President of Global Quality Assurance [HYPERLINK "mailto:adement@sterigenics.com"]
C: 908-240-8615

I stand ready with any assistance needed from me/us, Nelson English and Dr. Angelo Russo

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/15/2020 5:18:26 PM
To: Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
CC: Tabak, Lawrence A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0037b2fbba164f33a24944311b80393e-HHS-Lawrenc]; Anderson, James M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ae7a825549453d8398a1d93d3d7d21-HHS-james.a]; Santangelo, George M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ec58f11ceaa4e5693d795f544aecb4d-HHS-george.]
Subject: Re: Curated portfolio of preprints and publications on COVID-19

Thanks, Francis. This is very helpful.
Best
Steve

From: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Date: April 15, 2020 at 4:50:26 PM EDT
To: Redfield, Robert R (CDC) <olx1@cdc.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tabak, Lawrence A (NIH) <lawrence.tabak@nih.gov>, Anderson, James M (NIH) <james.anderson2@nih.gov>, Santangelo, George M (NIH) <george.santangelo@nih.gov>
Subject: Curated portfolio of preprints and publications on COVID-19

Dear Colleagues,

George Santangelo and his team members in our Office of Portfolio Analysis have developed a comprehensive, human-curated portfolio of COVID 19 publications and preprints: https://icite.od.nih.gov/covid19/search/ This includes peer-reviewed articles from PubMed and preprints from medRxiv, bioRxiv, ChemRxiv, and arXiv. It is updated daily and enables users to leverage the powerful iSearch platform to interrogate preprints, peer-reviewed publications, and all associated supplemental data from each. NIHers have found it extremely useful for querying what's already known about COVID 19 – so I thought I would pass it along to you also. Feel free to distribute!

Best, Francis

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 5:48:03 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; 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]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
Subject: Re: COVID-19 Task Force Briefing and Chloroquine Phosphate and Hydroxychloroquine Sulphate

Brett,
Thank you. This is great news.
Anand, is working with an inter-agency work group to organize the supply and supply chain of this drug so that it can be offered off label or on a large pragmatic clinical trial. Additional supply would be very helpful. Anand, would you take this from here?
Thanks
S

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 19, 2020 at 6:03:02 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>
Subject: FW: COVID-19 Task Force Briefing and Chloroquine Phosphate and Hydroxychloroquine Sulphate

FYSA

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Bradshaw, Sheldon <SBradshaw@KSLAW.com>
Sent: Thursday, March 19, 2020 2:28 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Sampson, Kyle <KSampson@KSLAW.com>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: COVID-19 Task Force Briefing and Chloroquine Phosphate and Hydroxychloroquine Sulphate

Admiral Giroir,

I hope my email finds you well. I wanted to write to you quickly regarding the COVID-19 task force briefing today. In their remarks President Trump and FDA Commissioner Hahn specifically mentioned Chloroquine Phosphate and Hydroxychloroquine Sulphate as possible treatments for COVID-19. As you are aware, these

2 drugs are used to fight malaria and autoimmune diseases, and have been in use for more than 70 years and are considered safe. And, importantly given the outbreak of COVID-19, researchers have discovered that Chloroquine Phosphate is effective at fighting the virus in studies done in test tubes, and at least 10 clinical trials are currently looking at the potential use of Chloroquine Phosphate as an option for combating COVID-19. See, e.g., Todar o, J., M.D., An Effective Treatment for Coronavirus (COVID-19) (Mar. 13, 2020).

I wanted to let you know that a long-time client, Ipca Laboratories Ltd. ("Ipca"), is a vertically integrated Indian pharmaceutical manufacturer that is the world's largest manufacturer of Chloroquine Phosphate and Hydroxychloroquine Sulphate active pharmaceutical ingredients ("APIs"). Ipca also holds FDA-approved abbreviated new drug applications ("ANDAs") for Chloroquine Phosphate Tablets and Hydroxychloroquine Sulphate Tablets. Headquartered in Mumbai, India, Ipca's manufacture of Chloroquine Phosphate and Hydroxychloroquine Sulphate APIs is not affected by the COVID-19's impact on the Chinese pharmaceutical supply chain. Of note, Ipca is projecting that, in the coming weeks, its U.S. sales of Chloroquine Phosphate API may increase approximately 900% (10x). On behalf of Ipca, and in the spirit of President Trump's statement that the United States "will remove or eliminate every obstacle necessary to deliver our people the care they need," I wanted to reach out to you to let you know that Ipca stands ready to assist FDA and other U.S. government officials in supplying Chloroquine Phosphate and Hydroxychloroquine Sulphate APIs and/or Chloroquine Phosphate and Hydroxychloroquine Sulphate Tablets to researchers, drug manufacturers, hospitals, pharmacies, government health agencies, and any others in need of this drug, should the need arise.

Please let me know if you have any questions or would like to discuss.

Sheldon

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 5:46:10 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: (b) (6) Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: (b) (6) < (b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

Steve we have been trying to work a fast track to get these prototype fabric masks evaluated for non-health care setting initially and ask that we consider a fast track for eval. Or is this a NIOSH action

---

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:54 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: FW: FDA Questions for your consideration re: Facemask

FYI-

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:52 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Mr. Cook,

Thank you for the response email. Once your team has had an opportunity to look at the link to the guidance document, let me know if you still have questions as relates labeling. It would be helpful for the team to know the planned indications for use for the product. The indications for use will assist in your labeling.

Have a nice evening.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-
I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:
1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)
4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).
5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?
6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?
7. How many enveloped viruses were tested?
8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.
10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.
13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.
14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

Let me know if you have any questions or concerns.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 6:45:23 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
Subject: RE: FDA Questions for your consideration re: Facemask

Sorry for the delay.

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 20, 2020 at 6:45:03 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: [redacted] Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thanks Steve and Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 20, 2020 6:03 AM
To: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: [redacted] (b) (6) Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>; Lloyd, Lindsay (FDA/CDRH) <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 20, 2020 at 6:03:05 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) [redacted] >, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

[redacted] (b) (5). Can the appropriate person or persons from your office hop on a call at 10:30 or 11 AM today so we can get a better sense of the clinical settings and parameters for use for the mask? A little guidance would help.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 5:46:13 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) (b) (6) Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
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Subject: RE: FDA Questions for your consideration re: Facemask

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Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:
1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)
4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).
5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?
6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?
7. How many enveloped viruses were tested?
8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.
10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.
13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.
14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

Let me know if you have any questions or concerns.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

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ADMINISTRATION

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/19/2020 1:38:05 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; lou.hayden@lowes.com; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Request for expedited FDA action for Hand Sanitizer - Moxie

For sure, Bob.
Mr. Hayden, I am connecting you with my deputy, Dr. Shah.
Best
Steve

Sent from my iPad

On Mar 19, 2020, at 12:44 PM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Steve can you advise who Mr Hayden from Lowe's could connect with th expedite review and approval

Sent from my iPhone

Begin forwarded message:

From: "Hayden, Lou" <lou.hayden@lowes.com>
Date: March 19, 2020 at 12:38:21 PM EDT
To: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Subject: Request for expedited FDA action for Hand Sanitizer - Moxie

Hello Dr. Kadlec – Good to talk with you briefly. During our CEO's call with the President on Tuesday, they asked for contact if we needed help on critical items.

Situation:
We have a found viable source for hand sanitizer out of Mexico and have validated their products. The quickest path to shelf/market is under our Private label Moxie. The vendor brand is registered only in Mexico, not in the US and this registration would take longer. Our Quality Assurance and Legal teams say that it will take 14 - 20 business days for the FDA to assign a labeler code (FDA certification number) and approval of our product label.

Ask:
Is there a contact we can work with at the FDA to expedite this process?

Please let me know how I can help.

Lowe's has 1,750 stores around the U.S. and 300,000 employees, and our products are "essential" for executing social distancing.

With warm regards,

Lou

Lou Hayden
Head of Washington, DC Office
Lowe's Companies
300 New Jersey Avenue NW, Ste. 900
Washington, DC 20001
202-464-2780

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 2:33:25 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; (b) (6) 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Debi Birx MD (b) (6) Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Jeff. Well done.
Steve

Sent from my iPad

On Mar 20, 2020, at 2:30 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

I wanted to let you know that we just got off the phone with the company. We found a glidepath for them to come to market now that would allow them to also market directly to healthcare facilities and healthcare workers with just a few disclaimers in their labeling and nothing else for them to do. They liked the idea. We're sharing that language with them now and otherwise they are good to go. They tell us they should be able to produce between (b) (4) masks per week starting in about two weeks and the possibility of being able to (b) (4)

Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 20, 2020 at 6:03:04 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

(b) (5). Can the appropriate person or persons from your office hop on a call at 10:30 or 11 AM today so we can get a better sense of the clinical settings and parameters for use for the mask? A little guidance would help.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 5:46:13 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: (b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

Steve we have been trying to work a fast track to get these prototype fabric masks evaluated for non-health care setting initially and ask that we consider a fast track for eval. Or is this a NIOSH action

---

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:54 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: FW: FDA Questions for your consideration re: Facemask

FYI-

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:52 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Mr. Cook,

Thank you for the response email. Once your team has had an opportunity to look at the link to the guidance document, let me know if you still have questions as relates labeling. It would be helpful for the team to know the planned indications for use for the product. The indications for use will assist in your labeling.

Have a nice evening.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
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Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-

I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

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Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

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Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
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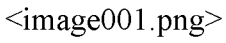
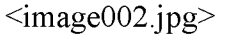
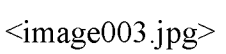
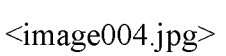
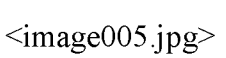
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

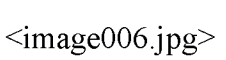












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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/15/2020 10:53:44 AM
To: Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Updated testing information

Paul,
As per our information. I called the relevant folks and go this information directly from the manufacturers.

Roche
Capacity 400,000 tests per week with a 3 month supply of reagents.
The test takes 3.5 hours to run although there would be more time needed to get results out to providers
This is a fully automated system
One potential issue is the plastic consumables - plastic plates. There is pressure on the supply chain and this could be aided by re-using the plates through proper cleaning. I've asked them to send an amendment to their EUA with a solution which we will review when it's available. They told me that they would call later today with an update. It's not urgent but something that would mitigate a POTENTIAL shortage

ThermoFisher
Capacity 1.4 million tests (they refer to these a reactions).
They can manufacture 2 million tests per week and the next batch can be sent out for use by the end of the week of March 23. That will be ongoing production.
A potential supply chain issue is the solvent prep for extraction of RNA. Their original EUA was done with validation for their own solvent but would like to expand that to other manufacturer's prep to mitigate any POTENTIAL shortage. This would include solvent prep from (b) (4) We are looking into whether that would require any regulatory approval. Should know something soon.
The installed base of instruments approved on the EUA is 340 labs in the 'hot spots.' They have additional installed base beyond the hot spots but he didn't have that info at his fingertips.
They want to expand that base to include forensics labs and are working on sending us validation data on this.
They also want to expand to a base that includes newer platforms that have not yet received FDA authorization but that (b) (4) have. (b) (4) are working on the validation tests to expand to this new base and he expects these data to be sent to FDA in the next few days. We will review expeditiously when we receive those data.

Please call with any questions.
Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/10/2020 10:23:31 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Polowczyk, John P ([redacted]
Subject: Re: Would ask your review

Bob,
I believe you are up to date on this. Keagan and our group can update you so that Hanes has all of the information needed to manufacture gowns.
Thanks
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 9, 2020 at 5:12:46 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Polowczyk, John P (MIL) [redacted]
Subject: FW: Would ask your review

Steve I wanted to let you know I have been working with Admiral P. on the cloth gowns with guess who? Hanes. They have a design that they are finalizing and they have suggested applying HeiQ VIroblock that would substitute for the copper-silver. This would help I think . I wanted to make you aware of this. It good advance the durability and address the issue of soiling. Best Bob

---

From: Kadlec, Robert (OS/ASPR/IO)
Sent: Tuesday, April 7, 2020 12:47 PM
To: Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; 'Hahn, Stephen' <SH1@fda.hhs.gov>
Subject: Would ask your review

Binita- I received updated technical data that was shared to me by the consortium making the 3 ply cotton facial coverings impregnating them with an alternative antimicrobial compound. I would appreciate understanding if this compound is already subject to FDA review and approval or potentially eligible for EUA status. Any concerns comment sor recommdnations you would have. Best Bob

The Agion compound is what is being used.

The proposed compound HeiQ
Thank you

Bob Kadlec

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/9/2020 5:42:36 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Polowczyk, John P (MIL) (b) (6)
Subject: Re: Would ask your review

Thanks Bob. Appreciate the call.
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 9, 2020 at 5:12:46 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/5/2020 8:48:13 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: [EXTERNAL] RE: Follow-up

You too, Bob. Take care

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 5, 2020 at 8:47:50 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Follow-up

Have a great COVID Free day

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, April 5, 2020 8:47 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Follow-up

Thanks

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 5, 2020 at 8:46:29 AM EDT
To: Hahn, Stephen (b) (6) @fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Follow-up

Yes

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, April 5, 2020 8:46 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: Follow-up

Bob,
Keagan and I will route this morning.
Thanks for alerting us.
Is (b) (6) from Walmart the appropriate person for us to contact?
Thanks again.
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 5, 2020 at 8:40:14 AM EDT

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen (b) (6) @fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Follow-up

Keagan and or Steve who would be appropriate to loop into this which is WALMART is willing to produce on scale cloth gowns and they seek a poc at FDA to coordinate on design cloth and treatment on such cloth is that Jeff Shueren?

From: Duffey, Michael P. EOP/OMB <(b) (6)
Sent: Sunday, April 5, 2020 8:31 AM
To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Cc: OS Farmer, Robert (b) (6) ; Swartz, Nathan M (MIL) (b) (6) >; Nelms, Jordan (DHS.GOV) (b) (6) @ Patrick Lake (b) (6)
Subject: Fwd: [EXTERNAL] RE: Follow-up

Paul/Bob/Brian - I am helping WalMart shift their production to make gowns. Can you help point me toward an FDA POC who can help make their requests below happen?

Sent from my iPhone

Begin forwarded message:

From: Deanah Baker <Deanah.Baker@walmart.com>
Date: April 4, 2020 at 7:49:49 PM EDT
To: "Duffey, Michael P. EOP/OMB" <M(b) (6) nb. >, Doug McMillon <McMillon.Doug@walmart.com>
Subject: [EXTERNAL] RE: Follow-up

Mike,
The task force is working very hard to both secure any finished PPE gowns available and find alternative fabrics that can be used for PPE gown production going forward.
Unfortunately, we are not moving fast enough and we need your help to progress with speed. My ask is that you help us secure the actions below.

(b) (4)

China is on holiday Sunday/Monday, but if we accomplish the above tomorrow, we will be prepared to move much faster, Tuesday, to immediately pick up any available inventory in the Chinese factories. We will also be able to quickly set up production of new gown fabrications in Central America.

I am available for a call anytime. (b) (6)
I will provide you a daily e-mail update as well.

Thank you,

Deanah

From: Duffey, Michael P. EOP/OMB (b) (6)
Sent: Saturday, April 4, 2020 4:47 PM
To: Deanah Baker <Deanah.Baker@walmart.com>; Doug McMillon <McMillon.Doug@walmart.com>
Subject: EXT: Follow-up

Doug/Deanah – I hope you are having a good Saturday. Just checking in to see how things are going and if there is anything further I can provide to help your efforts to ramp gown production.

Thank you again for your commitment to assist!

Sincerely,
Mike

_____

Mike Duffey
Program Associate Director for National Security Programs
Office of Management & Budget
The White House

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/5/2020 8:46:40 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: [EXTERNAL] RE: Follow-up

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Date: April 5, 2020 at 8:46:29 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Follow-up

Yes

From: Hahn, Stephen <SH1@fda.hhs.gov>
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Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 5, 2020 at 8:40:14 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Follow-up

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To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Cc: OS Farmer, Robert (b) (6) [redacted]; Swartz, Nathan M (MIL) (b) (6) [redacted]
Nelms, Jordan (DHS.GOV) <(b) (6) [redacted]; Patrick Lake (b) (6) [redacted]
Subject: Fwd: [EXTERNAL] RE: Follow-up

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Sent from my iPhone

Begin forwarded message:

From: Deanah Baker <Deanah.Baker@walmart.com>
Date: April 4, 2020 at 7:49:49 PM EDT
To: "Duffey, Michael P. EOP/OMB" <[redacted] (b) (6)>, Doug McMillon <McMillon.Doug@walmart.com>
Subject: [EXTERNAL] RE: Follow-up

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I am available for a call anytime. 479-790-2806.
I will provide you a daily e-mail update as well.

Thank you,
Deanah

From: Duffey, Michael P. EOP/OMB [redacted] Consult to OMB >
Sent: Saturday, April 4, 2020 4:47 PM
To: Deanah Baker <Deanah.Baker@walmart.com>; Doug McMillon <McMillon.Doug@walmart.com>
Subject: EXT: Follow-up

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Mike

Mike Duffey
Program Associate Director for National Security Programs
Office of Management & Budget
The White House

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/5/2020 8:45:46 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
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Cc: OS Farmer, Robert <(b) (6) ; Swartz, Nathan M (MIL) (b) (6) ; Nelms, Jordan (DHS.GOV) (b) (6) >; Patrick Lake <(b) (6) >
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I am available for a call anytime. (b) (6)
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From: Duffey, Michael P. EOP/OMB (b) (6)
Sent: Saturday, April 4, 2020 4:47 PM
To: Deanah Baker <Deanah.Baker@walmart.com>; Doug McMillon <McMillon.Doug@walmart.com>
Subject: EXT: Follow-up

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Thank you again for your commitment to assist!

Sincerely,
Mike

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Mike Duffey
Program Associate Director for National Security Programs
Office of Management & Budget
The White House

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/3/2020 11:59:04 AM
To: Hayden, Lou [lou.hayden@lowes.com]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: Russo, Joseph H. EOP/WHO (b) (6) Tim Pataki (b) (6)]
Subject: Re: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

Lou
How very kind of you. I'll leave this to Bob to respond. Congratulations on your terrific work
Steve

From: Hayden, Lou <lou.hayden@lowes.com>
Date: April 3, 2020 at 11:33:19 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: Russo, Joseph H. EOP/WHO <(b) (6) , Tim Pataki <(b) (6) >
Subject: A victory! New sanitizer supplies coming nationwide. Thank you. Question on donation?

Drs. Hahn, Shah, and Kadlec, and Joe and Tim –

Thank you for your attention to help prioritize the expedited and thorough review for FDA approval for new Moxie-brand hand sanitizer to serve our 18 million customers a week nationwide, including first responders nationwide.

By the time the product flows into our distribution / store network, it will be early May.

Question: Since the government may have ongoing demand for essential materials, could we make a direct donation of 10,000 of the first units of hand sanitizer when they arrive in early May?

(Lowe's has already made $175 million in COVID-related contributions, including $10 million in products to responders, $ to the Red Cross, donating all N-95 masks, and direct cash bonuses to our working hourly employees.)

With warm regards,

Lou

Lou Hayden
Head of Washington, DC Office
Lowe's Companies
300 New Jersey Avenue NW, Ste. 900
Washington, DC 20001
202-464-2780

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/5/2020 9:17:59 AM
To: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; (b) (6) OS/IOS) (b) (6)@HHS.GOV]
CC: Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]
Subject: Re: 4.4.20 Open Letter from Gilead CEO Daniel O'Day re: remdesivir

Mr. Secretary,
Janet and I are aware and I'm available to you for an update at any time.
thanks
Steve

From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Date: April 4, 2020 at 7:30:30 PM EDT
To: AMA2 (OS/IOS) <AMA2@HHS.GOV>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Charrow, Robert (OS) <Robert.Charrow@hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Stecker, Judy (OS) <Judy.Stecker@hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Trueman, Laura (OS) <Laura.Trueman@hhs.gov>
Subject: Fwd: 4.4.20 Open Letter from Gilead CEO Daniel O'Day re: remdesivir

Begin forwarded message:

From: Chuck Clapton <Chuck.Clapton@gilead.com>
Date: April 4, 2020 at 7:23:09 PM EDT
To: "Pataki, Timothy (b) (6)" (b) (6) "Pinkos, Stephen (b) (6) (b) (6), (b) (6), "(b) (6)" (b) (6), "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>, "Pence, Laura (HHS/ASL)" <Laura.Pence@hhs.gov>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Disbrow, Gary (OS/ASPR/BARDA)" <Gary.Disbrow@hhs.gov>
Cc: Michael Boyd <michael.boyd1@gilead.com>
Subject: 4.4.20 Open Letter from Gilead CEO Daniel O'Day re: remdesivir

Attached is an open letter that Gilead Chairman and CEO Daniel O'Day just sent out regarding the latest developments on remdesivir. It includes an update on Gilead's compassionate use and expanded access programs (approximately 1,700 patients have received remdesivir through these programs), Gilead's ongoing efforts to expand its capacity to manufacture remdesivir, and Gilead's intent to donate our entire existing supply of remdesivir (approximately 1.5 million doses which equals more than 140,000 treatment courses for patients) to treat patients with the most severe symptoms of COVID-19. For reference, I have also copied below a link to Gilead's twitter account where you can also find the letter.

If you have any questions, please do not hesitate to call/text/email. Thanks

Chuck
Direct: 202-774-5936
Cell: 202-669-2316

https://protect2.fireeye.com/url?k=9a7584b7-c621ad9c-9a75b588-0cc47a6d17cc-825e4fc38b4aef7f&u=https://www.gilead.com/stories/articles/an-update-on-covid-19-from-our-chairman-and-ceo

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/23/2020 7:52:21 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043[redacted](b) (6)lahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1[redacted](b) (6) Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]
Subject: FW: as discussed

You fellows have familiarity with any of these tests pasting in additional email form this chap

On the test kit from BG - should receive FDA approval on Wednesday or Thursday. With your nod, I am pretty sure we can commandeer the full 4 and 8 week requirement before they ship elsewhere.

From: Sam Fairchild <[redacted](b) (6) com>
Sent: Monday, March 23, 2020 7:34 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: Re: as discussed

Focusing the search now. Also, is this on your radar? Danish manufacturer, manufacturing site in Wuhan.

Real-time fluorescent RT-PCR kit for detecting 2019-nCoV
【Generic product name】
Real-time fluorescent RT-PCR kit for detecting 2019-nCoV
【Package size】 50 tests/kit
【Catalogue Number】 MFG030010
【Intended use】
The kit is a qualitative in vitro nucleic acid amplification assay to detect the new coronavirus identified in China in 2019 using Reverse transcription PCR in specimen of throat swab and Bronchoalveolar Lavage Fluid (BALF)from suspects.
In end of 2019, some pneumonia cases were reported in Wuhan, China and the pathogen was confirmed as a new strain. World Health organization has named the newly identified coronavirus as 2019-nCoV. Although more intensive researches must be conducted later to well understand the virus, in response to the emergency in disease control, simple and rapid kit is necessary to identify the virus timely and implement efficient interventions to contain the spread. The kit will qualitatively detect the nucleic acid of 2019-nCoV in specimen from suspects enabling to assess the infection situation of 2019-nCoV in suspects in clinical and public health practice.
【Principle of the procedures】
The kit is based on in vitro RT-PCR combining fluorescent probing. Primers and a sequence-specific fluorescence probes were designed tailored to high conservative region in 2019-nCoV genome. The probes are oligonucleotide attached fluorophores at the 5' end with FAM as reporter and 3' end with quencher. In a meantime, specific primers and probes were developed as internal reference with fluorophores VIC/HEX attached at 5' end as reporter. During the PCR procedures, the DNA polymerase cleaves the probe at the 5' end and separates the reporter dye from the quencher dye when the probes hybridize to the target DNA. This cleavage results in the fluorescent signal generated by the cleaved reporter dye, which is monitored real-time by

the PCR detection system. Monitoring the fluorescence intensities during Real Time allows the qualitative detection of 2019-nCoV in specimens.

【Key contents】

Item(50 tests/kit)
Specification
Quantity
Description

2019-nCoV Reaction Mix
1mL /vial
1 vial
Composed of reagent for amplification and probes and primers of target gene and internal reference

2019-nCoV Enzyme Mix
80μL /vial
1 vial
Taq polymerase, Reverse transcriptase and UDG

2019-nCoV Positive control
750μL/vial
1 vial
Mix solution of pseudo-virus with target virus genes and internal reference

2019-nCoV Blank control
750μL/vial
1 vial
DNase/RNase free water

Materials required but not provided

• Reagents:TIANamp Virus RNA extraction Kit (DP315-R) manufactured by TIANGEN, or QIAamp Viral RNA

Mini Kit (52904) by QIAGEN.

• 1.5 mL RNase/DNase-free microcentrifuge tube, RNase/DNase-free tips for pipettes, 0.2mL 8-tube strips for real-time PCR, Bench centrifuge, Vortex mixer.

• Notes:Components contained within a kit are intended to be used together. Do not mix components from different kit lots.

【Storage and shelf-life】

• The RT-PCR Kit should be stored at temperature lower than -18°C in dark. It is stable with shelf-life at 2-8 °C for 5 days and at -18°C for 6 months(tentative). Unpacked kit should avoid repeated thaw-freeze cycle (within 4 times)

• The PCR Kit can be transported at -18°C in dark stable for 5 days. The manufacture date and shelf life would be provided in the labelling.

【Applicable instruments】

Applied BiosystemsTM Real time PCR system 7500; SLAN-96P PCR system

【Specimen】 Sample collection

• Collect fresh specimen of throat swabs and BALF from suspects. The operation of specimen should avoid possible contamination in collection, storage and transportation. The specimen should be presumed contagious and be operated according to related regulations.

• Throat swabs: Carefully take out the swab from package and quickly rotate it around two sides of fauces, throat and tonsil a few times applying pressure to collect as much secretions as possible. Avoid touching tongue. Break the swab stick and put the head into sampling solution in specimen tubes. Screw the tube cap tightly to ensure no leakage.

• BALF: Collect 3ml of unprocessed BALF in sterile, dry and clean DNase/RNase free Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film.

Storage

• The specimen should be kept in proper condition, at -18°C for not longer than 1 weeks and at -70°C for not longer than 6 months.
• Frozen specimen should be thawed thoroughly while avoiding repeated thaw-freeze cycle.
Transportation
• The specimen should be shipped in low temperature condition using dry ice or ice bag.
【Laboratory procedures】(Please read the procedures carefully before your operation)
Sample processing
• The fresh specimen should be collected to ensure the qualified RNA in terms of quality and quantity for the

assay. RNA should be extracted using Nucleic Acid extracting Kit in line with the manufacturer's instruction. Equivalent volume of positive control and blank control should be processed simultaneously. The assay was validated by the recommended RNA extraction kits by TIANGEN (DP315-R)and QIAGEN(52904).
• The extracted RNA should be tested immediately or stored at -70°C for test later.
Reagent preparation
• Take out all the kit contents and thaw them thoroughly at ambient temperature. Vortex and centrifuge briefly. The Enzyme Mix should be kept in ice continuously.
• Estimate the number of reactions (N) in the test, which includes the number of Blank control (1 tube), Positive control (1 tube), and specimens prepared. Prepare 8-tube strips for PCR based on the estimated N of reaction and develop the PCR mix as ingredients in following table. Pipette 20μL PCR Mix per tube into the 8-tube strips. Capped them fastened and transfer them to sample processing Area. The remaining Nucleic acid reaction Mix and Enzyme Mix should be stored at -18°C immediately.
Add sample
• Add 10μL the extracted RNA of specimens, Blank control and Positive controls respectively into the 8-tube strips
prefilled with PCR Mix. Capped them fastened and centrifuge them at 2000rpm for 10 seconds. Place the tubes into thermal cycler and record the exact location of controls and every specimen.
Real time PCR
• Set the fluorescent channels:Please refer to the manufacturer's instructions of thermocycler for detailed information on channel setting.
FAM channel (Reporter: FAM, Quencher: None) for RNA of 2019-nCoV;
VIC/HEX channel(Reporter: VIC/HEX, Quencher: None) for internal reference; Reference Dye:None(only for ABI PCR system);
Sample Volume: 30.
• Configure PCR protocol

2019-nCoV Reaction Mix(μL)	2019-nCoV Enzyme Mix(μL)	PCR-Mix (μL)
18.5×N	1.5×N	

Step	Cycle	Temperature	Duration	Fluorescence measured(Y/N?)
1	1 cycle	50°C	20minutes	N
2	1 cycle			

95°C
10minutes
N
3
40cycles
95°C
15 seconds
N
60°C
30 seconds
Y
Data analysis

- Baseline and threshold for ABI7500 PCR system

Baseline starting point at 3 and ending at 15
The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, the blank control should be selected firstly and click off the Automatic standard curve by changing the option from "□√Auto" to "□Auto". Set the threshold manually just above the maximum level of blank control curve (random noise curve) at FAM channel.

- Data from SLAN-96P PCR system

The starting and ending points of baseline should be set as 6 and 12 respectively.
The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, change the configuration of baseline optimization in basic parameter from automatic to manual. Then, manually set the threshold just above the maximum level of blank control curve (random noise curve) at FAM/ VIC(HEX).
Quality control

- Blank control: Ct values at FAM and VIC/HEX channels are 0 or no data available.
- Positive control:Standard curves at channel FAM and VIC/HEX channels are in S-shape with Ct values not higher than 32.
- Testing specimen: Standard curves at VIC/HEX channel is in S-shape with Ct not higher than 32.
- Above requirements should be met in a single test. Otherwise, the test is invalid. Please operate the retest strictly

in line with the package insert.
【Threshold and reference range】

- Cut-off value of the kit was determined based on the Receiver Operator characteristic curve from testing clinical

samples. Ct value for 2019-nCoV positive by the kit is not high than 38.
【Testing result interpretation】

- The specimen is positive of 2019-nCoV if standard curve at FAM channel is in S-shape with Ct value not higher

than 38.

- The specimen is negative of 2019-nCoV if standard curve at FAM channel is not in S-shape with Ct at FAM as 0 or no data available while Ct at VIC/HEX not higher than 32.
- The specimen should be retested if standard curve at FAM is in S-shape with Ct higher than 38. The specimen can be reported on basis of retesting results as positive of 2019-nCoV for Ct higher than 38 and as negative of 2019-nCoV for standard curve not in S-shape and Ct of internal reference not higher than 32 at VIC/HEX.
- In case that standard curve at FAM is not in S-shape with Ct value as 0 or no data available, the specimen should be retested if Ct at VIC is higher than 32 or no data available.

【Limitation of the assay】

- The Results of the test is just for information in clinical practices to assess infection condition of patients combining

with clinical presentations and other laboratory markers.

- The incorrect result can be caused by incorrect operations in sample collection, transportation or processing, very low concentration of target virus in the specimens, mutations within the viral genome covered by the kit's primers and/or probe, and unproved external interference factors, such as PCR inhibitor.

【Performance characteristics】

- The package is intact and liquid contents are clear, transparent and no sediments. All contents are in correct quantity as the package insert listed.
- Positive control is positive at both FAM and VIC/HEX channel in testing while blank control is negative at both channels.
- Limitation of Detection (LOD) of the kit is 100 copies/mL for detecting 2019-nCoV.
- The kit was validated by national positive and negative standards.
- A potential cross-reactivity of the RT-PCR Kit was tested and none of the tested pathogens and human gene have been reactive. The tested pathogens include 54 pathogens, such as human coronavirus includes OC43,229E, HKU1 and NL63(HCoV-OC43, HCoV-229E, HCoV-HKU1, HCoV-NL63) and other pathogens.
- The reproducibility of the assay was validated by manufacturer's precision standards (CV1 and CV 2), LOD standard and negative standard. All samples were tested repeatedly for 20 times, respectively. Coefficient of variance (CV) for Ct values were analyzed to evaluate the variability of inter- and intra-batches, within day and day-to-day operation. The CVs are all less than 5% respective (n=20).
- The repeatability of assay was validated by manufacturer's repeatability standards, LOD standard and negative standard repeatedly for 20 times. Coefficient of variance (CV) for Ct values were analyzed to evaluate the inter- batch variability. They are all less than 5%.
- Interference trial shows that performance of the kit is stable with endogenous and exogenous interfering substances such as some anti-microorganism drugs, nasal sprays and nasal drops in specimen. Specimen with elevated level of mucoprotein at a concentration of 60 mg / mL and other substances do not influence the kit performance at virus concentration higher than Limit of Detection.

【Warning and precautions】

- FOR IN VITRO TEST ONLY. Please read the package insert carefully before your operation. The appropriate operations from specimen collection, storage and transportation, and laboratory test should be strictly manipulated in line with relevant regulations of biosafety and molecular laboratory management. Please contact BGI sales for the most up-to-date information in the event of damage to the protective packaging
- The false positive or negative testing result can be led by poor quality of specimen, incorrect operations in sample collection, transportation or laboratory processing, or limitation of the technology. Operator should understand well the principles of the procedures and its limitation in performance in advance and avoid any potential mistakes intentionally.
- Separate laboratory areas are recommended to performing predefined procedures of the assay.

a) 1st Area:Preparation Area—Prepare testing reagent;
b) 2nd Area:Sample processing—Process the specimen and controls;
c) 3rd:Amplification Area—PCR conducted.

- All materials used in one area should always be remained in the area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected timely.
- All contents in the package are prepared dedicatedly for the intended testing purpose and validated. Replacing any of them will affect the testing performance of the kit. Components contained within a kit are intended to be used together. Do not mix components from different kit lots.
- Thaw all kit components thoroughly and centrifuge them briefly before starting an assay. Avoid repeated thaw- freeze cycle.
- 8-tube strips for real time PCR capped fasten and transferred to specimen processing area immediately after addition of Nucleic Acid reaction Mix.

• To prevent the contamination from exogenous RNA, sample addition should follow the sequence of negative control, specimen RNA and positive control. Filtered tips should be prepared and used separately in preparing reagent and sample addition.
• Ensure to pipette the samples exactly into the reaction mix in PCR tubes and avoid sticking the samples to the inside tube wall. The tubes should be capped fasten immediately after the addition.
• After the protocol of amplification is done, remove PCR tubes from the thermal cycler and discard them in a sealable plastic bag for autoclave and decontamination.
• Ensure no foam or bubbles present in the tubes when aliquoting nucleic acid Mix. All PCR tubes capped fasten before loading them into the thermal cycler to avoid any possible leakage and contamination.
• The workbench and lab supplies should be cleaned and disinfected regularly using 75% ethanol or UV light.
• All pipette tips and centrifuge tubes in the assay should be DNase/RNase-free. The used centrifuge tubes and pipette tips should be discarded in waste bin with Clorox (84) disinfectant and disposed with other laboratory wastes after decontamination.
• Operator should receive professional training before operating.

【References】

[1] LU Rou-jian, ZHANG Ling-lin, TAN Wen-jie, ZHOU Wei-min, WANG Zhong, PENG Kun, RUAN Li. Development
and Comparison of Real-Time and Conventional RT-PCR Assay for Detection of Human Coronavirus NL63 and HKU1[J]. CHINESE JOURNAL OF VIROLOGY, 2008(4).
[2] NIU P, LU R, LAN J, LIU G, WANG W, TAN W. Development of Novel Multiplex Real-time RT-PCR Assays for Detection of MERS-CoV Infection[J]. CHINESE JOURNAL OF VIROLOGY, 2016(3).

[3] CHEN Yu-jing. Development of two-panel reactions of real-time PCR for detection of 18 types/subtypes of respiratory viruses[D]. 2015

【Contact details】 Manufacturer: BGI Europe A/S
Manufacturer Address: Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark
Manufacturing Site: BGI Biotechnology (Wuhan) Co.,Ltd
Site Address: Building B2, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan
Please contact:
BGI Europe A/S
Service hotline:
Copenhagen, Denmark: 0045-80300800/ 0045-70260806
Website:https://protect2.fireeye.com/url?k=19662191-453238ed-196610ae-0cc47adc5fa2-7c907fa3556bef91&u=http://www.bgi.com/

【Language edition】

For the requirements of Instruction for Use in other languages, please contact BGI Europe A/S.

【Release date of the user manual】

This manual was released on 2020-02-26

【Key to symbols used】

IN VITRO DIAGNOSTIC MEDICAL DEVICE
MANUFACTURER
USE BY DATE
BATCH CODE
DATE OF MANUFACTURE
CATALOGUE NUMBER

CAUTION
UPPER LIMIT OF TEMPERATURE
CE MARK
CONSULT INSTRUCTIONS FOR USE

KEEP AWAY FROM SUNLIGHT
KEEP DRY
DO NOT RE-USE
POSITIVE CONTROL
CONTAINS SUFFICIENT FOR N TESTS

Sent from my iPhone

On Mar 23, 2020, at 6:59 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Sam thanks this is great news. You can drop the ventilators for the moment as we are working domestic producers gloves glasses face shield and Tyvek like suits are the high priority need.

Sent from my iPhone

On Mar 22, 2020, at 11:56 PM, Sam Fairchild <samchild7@gmail.com> wrote:

Bob - David has set up SinoPharma and JY Pharma as the two procurement throats for the supplies and equipment. This serves three purposes -- first, they will certify that supplies moving through the procurements meet FDA standards (weeding out non-compliant materials) and serve as quality control thereof. Second, they are capable of providing the necessary working capital to procure and stage materials in concert with HHS procurement terms. Third, they will not be hindered by customs bureaucrats and others who may delay movements. I should see detailed quotes on certain items in the next 24 - 48 hours.

I do need some more detailed specs on several items -- glove standards, respirator specs and ventilator specs -- can you get someone to send me the next layer down on these.

It looks quite hopeful on being able to fulfill your 4 week and 8 week lists.

Let me know on those specs. Also, can someone send me a sample HHS purchase order to lays out payment terms so I can preposition that for acceptance in China?

All the best, my friend. Keep up the impossibly good job that you all are doing! A grateful nation and all that!! Sam

On Thu, Mar 19, 2020 at 6:50 PM Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/20/2020 6:44:28 AM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Cook, Jerry [Jerry.Cook@hanes.com]
CC: (b) (6) 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]
Subject: RE: FDA Questions for your consideration re: Facemask

Jeff I am copying the Haines POC (Jerry Cook) and will call him to have his team do this. Bob

---

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Friday, March 20, 2020 6:03 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>; Lloyd, Lindsay (FDA/CDRH) <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

(b) (5). Can the appropriate person or persons from your office hop on a call at 10:30 or 11 AM today so we can get a better sense of the clinical settings and parameters for use for the mask? A little guidance would help.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 5:46:13 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: [redacted] (b) (6) < [redacted] (b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

Steve we have been trying to work a fast track to get these prototype fabric masks evaluated for non-health care setting initially and ask that we consider a fast track for eval. Or is this a NIOSH action

---

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:54 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: FW: FDA Questions for your consideration re: Facemask

FYI-

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:52 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Mr. Cook,

Thank you for the response email. Once your team has had an opportunity to look at the link to the guidance document, let me know if you still have questions as relates labeling. It would be helpful for the team to know the planned indications for use for the product. The indications for use will assist in your labeling.

Have a nice evening.

With Respect,

Liz

Elizabeth F. Claverie-Williams, MS

CAPT, USPHS-CC, Microbiologist

Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-6298

Elizabeth.Claverie@fda.hhs.gov

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-

I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:

1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)

4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).

5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?

6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?

7. How many enveloped viruses were tested?

8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.

10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.

13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.

14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

Let me know if you have any questions or concerns.

With Respect,

Liz

Elizabeth F. Claverie-Williams, MS

CAPT, USPHS-CC, Microbiologist

Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection

DHT4B: Division of Infection Control and Plastic Surgery Devices

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Ph: 301-796-6298

Elizabeth.Claverie@fda.hhs.gov

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/20/2020 2:36:35 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; (b) (6); 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; (b) (6) Who Abbott (b) (6)
Subject: Re: FDA Questions for your consideration re: Facemask

Jeff thanks great news. Thank you for efforts with them.

Sent from my iPhone

On Mar 20, 2020, at 2:30 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wro

I wanted to let you know that we just got off the phone with the company. We found a glidepath for them to come to market now that would allow them to also market directly to healthcare facilities and healthcare workers with just a few disclaimers in their labeling and nothing else for them to do. They liked the idea. We're sharing that language with them now and otherwise they are good to go. They tell us they should be able to produce between (b) (4) masks per week starting in about two weeks and the possibility of being able to (b) (4)

Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 20, 2020 at 6:03:04 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) (b) (6) Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
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Liz

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Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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https://www.research.net/s/cdrhcustomerservice?ID=1622&S=E

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>;

Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-

I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:

1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)

4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).

5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?

6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?

7. How many enveloped viruses were tested?

8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.

10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.

13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.

14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

Let me know if you have any questions or concerns.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

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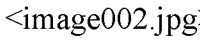

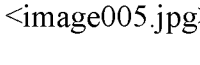

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/9/2020 5:11:04 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Polowczyk, John P (MIL) (b) (6)
Subject: FW: Would ask your review
Attachments: Agion AM-B10G Slurry TDS Rev 0 (002).pdf; Agion Data File 03212020-V1.pdf; Agion Data File 03222020-Full.pptx; Redacted SARS Test Report.pdf; Gerba-Antiviral Properties of Agion.pdf; 20200320_ViroblockStudies_summary.pdf; AGS20WP lbl 21 02 2013 part 1.pdf; AGS20WP lbl 21 02 2013 part 2.pdf; HeiQ_ Pure TAG_ Final Label 2019 - Copy.pdf; HeiQViroblock_FDA_Questions.pdf

Steve I wanted to let you know I have been working with Admiral P. on the cloth gowns with guess who? Hanes. They have a design that they are finalizing and they have suggested applying HeiQ VIroblock that would substitute for the copper-silver. This would help I think . I wanted to make you aware of this. It good advance the durability and address the issue of soiling. Best Bob

---

From: Kadlec, Robert (OS/ASPR/IO)
Sent: Tuesday, April 7, 2020 12:47 PM
To: Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; 'Hahn, Stephen' <SH1@fda.hhs.gov>
Subject: Would ask your review

Binita- I received updated technical data that was shared to me by the consortium making the 3 ply cotton facial coverings impregnating them with an alternative antimicrobial compound. I would appreciate understanding if this compound is already subject to FDA review and approval or potentially eligible for EUA status. Any concerns comment sor recommdnations you would have. Best Bob

The Agion compound is what is being used.

The proposed compound HeiQ
Thank you

Bob Kadlec

TECHNICAL DATA SHEET

Agion® AM-B10G Slurry

Description: Agion® AM-B10G Slurry is a textile finishing agent that provides excellent antimicrobial performance to a wide variety of fabrics. It is a bluish tinted, aqueous based dispersion with type A zeolite powder containing ionic silver and copper. Agion® AM-B10G Slurry has an acrylic resin base so that no additional components are required. This formulation has been designed for use on fabric, garment and other similar applications. Agion AM-B10G is free of Zinc.

Product Specification: The material is tested according to the test procedure included in the *"Inspection Standard"*, and must comply with the following specification values:

Parameter	Analytical Method	Unit	Specification Value
Copper Content	Atomic Absorption	Wt%	0.63-0.89
Silver Content	Atomic Absorption	Wt%	0.65-0.93
Particle Size Distribution	Laser Particle Analysis	µm	Mean less than 5
Percent Solids	Gravimetric Analysis	Wt%	35-50%

Typical Properties*:

Appearance	Blush tint dispersion
Crystal Structure of Solids	Type A Zeolite
pH in water	6-9
(Weight per gallon, lb. @25°C	~9

These items are provided as general information only. They are approximate values and are not considered part of the product specification.

Storage and Handling:

Agion® AM-B10G Slurry should be stored in a tightly closed corrosion resistant containers to prevent evaporation of water and the introduction of contaminants that can adversely affect performance.

Do not store below 40° F (4°C) to protect from freezing or above 104°F (40°C) to maintain product quality.

Agion® AM-B10G Slurry should be thoroughly mixed prior to use to ensure a uniform dispersion, since settling will occur during prolonged storage. Particular attention should be paid to the bottom of the container to ensure homogeneous composition. In the case of large storage containers like totes, it is recommended to mix the tote with a suitable motor driven mixer, electric or air powered, at least once per day for approximately 30 minutes prior to use.

Do not use galvanized fittings or connections with AM-B10G. Only use stainless steel or PVC.

Further dilution of slurry with a suitable solvent may reduce the stability of the dispersion and continuous agitation during processing may be required to ensure uniform distribution.

Because Sciessent LLC does not control the use, processing or method of use to which others may put its antimicrobial agents, Sciessent does not guarantee the effectiveness or suitability of the agents for use in any particular process, application or article of manufacture. These agents are not suitable for or efficacious in all applications to which a user may desire to apply them. The user of any agent described in this Technical data Sheet should conduct their own tests to determine the suitability of the agent in their particular process, application or article of manufacture.

Sciessent LLC warrants that its products in the original, sealed containers will meet the product specifications for a period of three (3) months from the date of Shipment.

SCIESSENT DISLCAIMS ALL WARRANTIES, WHETHER EXPRESSED, IMPLIED, OR STATUTORY, INCLUDING THE WARRANTIES OF MECHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT SHALL SCIESSENT BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES HOWSOEVER ARISING. BUYER'S SOLE AND EXCLUSIVE REMEDY AGAINST SCIESSENT FOR ANY CAUSE OF ACTION ARISING OUT OF THE SALE OR USE OF ANY PRODUCT HEREIN DESCRIBED SHALL BE REPLACEMENT OF THE PRODUCT OR REFUND OF THE PURCHASE PRICE PAID FOR THE PRODUCT.

Sciessent

Agion AM-B10G

Michael D. Abbott

Michael.Abbott@Hanes.com

03/21/2020

Outline

Agion Chemistry Summary

- Company
  - Sciessent
    - www.sciessent.com
- Chemical Name
  - Agion AM-B10G
  - Application rate
    - 1.50% OWG(on weight of goods)
    - Grams/Sq Meter will be supplied by Sciessent
- TDS/SDS is attached
- Application method will be provided by Sciessent based on available equipment
  - Exhaust
  - Pad
  - Foam
  - Etc.
- Sales Contact
  - Meg McComb
  - mmccomb@sciessent.com
  - Mobile: (339) 293-9097
- Technical Support
  - Frank Stevens
  - fstevens@sciessent.com
  - Mobile: +1 (562) 343-4199

AGION AM-B10G

SDS

SCIESSENT LLC

Safety Data Sheet
Agion® AM-B10G Slurry

SECTION 1: Identification

Product identifier

Product name	Agion® AM-B10G Slurry
Brand	Agion®

Other means of identification
Antimicrobial treatment for textiles

Supplier's details

Name	Sciessent LLC
Address	100 Cummings Center Suite 251-G Beverly, MA 01915 USA
Telephone	781-224-7100
email	EHS coordinator - Info@sciessent.com

Emergency phone number(s)

Chem TREC (24 hour) 1-800-424-9300 or +1-703-527-3887

SECTION 2: Hazard identification

General hazard statement
Hazardous to the aquatic environment, short term, acute. Category 1.
Hazardous to the aquatic environment, long-term, chronic. Category 2.

Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

GHS label elements, including precautionary statements

Pictogram

Hazard statement(s)

H400	Very toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects

Precautionary statement(s)

P273	Avoid release to the environment.
P391	Collect spillage.
P501	Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

SECTION 3: Composition/information on ingredients

Mixtures

Hazardous components

1. Silver copper zeolite

Concentration	10 - 15 % (weight)
CAS no.	130328-19-7

2. Silver zeolite

Concentration	5 - 10 % (weight)
CAS no.	130328-18-6

3. Water

Concentration	50 - 60 % (weight)
EC no.	231-791-2
CAS no.	7732-18-5

4. Acrylic polymer resins

Concentration	20 - 30 % (weight)
CAS no.	38054-57-8

5. Propylene glycol

Concentration	1 - 3 % (weight)
EC no.	200-338-0
CAS no.	57-55-6

6. Polyurethane resin

Concentration	1 - 2 % (weight)
CAS no.	67700-43-0

SECTION 4: First-aid measures

Description of necessary first-aid measures

If inhaled	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

In case of skin contact	Immediately wash skin with soap and plenty of water. Get medical attention if irritation develops or persists.
In case of eye contact	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Remove contacts if present and easy to do. Continue rinsing. Get medical attention, if irritation or symptoms of overexposure persists.
If swallowed	If swallowed, do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

Personal protective equipment for first-aid responders

As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Most important symptoms/effects, acute and delayed
Refer to Section 2 and/or Section 11.

Indication of immediate medical attention and special treatment needed, if necessary
None.

SECTION 5: Fire-fighting measures

Suitable extinguishing media
Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.

Specific hazards arising from the chemical
None

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures
Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Use proper personal protective equipment as listed in Section 8.

Environmental precautions
Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up
SMALL SPILLS: Contain and absorb with absorbent material and place into containers for later disposal. Wash site of spillage thoroughly with water. LARGE SPILLS: Dike far ahead of spill to prevent further movement. Recover by pumping or by using a suitable absorbent material and place into containers for later disposal. Dispose in suitable waste container.

Reference to other sections
For disposal see section 13.

SECTION 7: Handling and storage

Precautions for safe handling
Use with adequate ventilation. Avoid breathing vapor and contact with eyes, skin and clothing.

Conditions for safe storage, including any incompatibilities
Store in a cool, dry, well ventilated area away from sources of heat, combustible materials, and incompatible substances. Keep container tightly closed when not in use.
Do not store below 40° F (4° C) to protect from freezing or above 120°F (50° C) to maintain product quality.
Store in a tightly closed corrosion resistant container to prevent evaporation of water and the introduction of contaminants that can adversely affect performance.

Specific end use(s)
Slurry should be thoroughly mixed prior to use to ensure uniform dispersion, since settling will occur during prolonged storage. Particular attention should be paid to the bottom of the container to ensure homogeneous composition.

SECTION 8: Exposure controls/personal protection

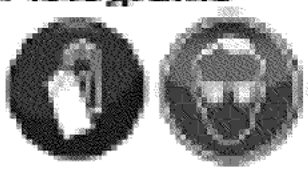
Control parameters

1. Propylene glycol (CAS: 57-55-6 EC: 200-338-0)
TWA (Inhalation): 10 mg/m3; USA (OSHA)
USA. Workplace Environmental Exposure Levels (WEEL)

Appropriate engineering controls
Use appropriate engineering controls such as process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Good general ventilation should be sufficient to control airborne levels. Where such systems are not effective wear suitable personal protective equipment, which performs satisfactorily and meets OSHA or other recognized standards. Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Individual protection measures, such as personal protective equipment (PPE)

Pictograms



Eye/face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Chemical-resistant gloves and chemical goggles, face-shield and synthetic apron or coveralls should be used to prevent contact with eyes, skin or clothing.

Body protection
Chemical-resistant gloves and chemical goggles, face-shield and synthetic apron or coveralls should be used to prevent contact with eyes, skin or clothing.

Respiratory protection
Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance/form (physical state, color, etc.)	Blue Slurry
Odor	Not determined.
Odor threshold	Not determined.
pH	7 - 9
Melting point/freezing point	Not determined.
Initial boiling point and boiling range	> 100 C
Flash point	> 100 C
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable
Upper/lower flammability limits	Not applicable
Vapor pressure	Not determined.
Vapor density	Not determined.
Relative density	~9 lbs/gal (1.07 g/cm3) @25°C
Solubility(ies)	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined.
Viscosity	Not applicable
Explosive properties	Not determined.
Oxidizing properties	Not determined.

SECTION 10: Stability and reactivity

Reactivity
No data available

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
None under normal use conditions.

Conditions to avoid
Heat, flames, and incompatible materials. Temperature below 40° F (4° C) or above 120°F (50° C).

Incompatible materials

Propylene glycol: Acid chlorides, Acid anhydrides, Oxidizing agents, Chloroformates, Reducing agents

Hazardous decomposition products

Water: In the event of fire: see section 5

Propylene glycol: Other decomposition products - No data available
In the event of fire: see section 5

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity
Silver Copper Zeolite:
Inhalation: Inhalation Rat LC50: > 2.59 m g/L/4hr (Manufacturer Studies)
Ingestion: Ingestion Rat LD50: > 5 gm/kg (Manufacturer Studies)

Silver Zeolite :
Dermal Rat LD50: > 2 gm/kg
Ingestion Rat LD50: > 5 gm/kg (Manufacturer Studies)
Inhalation Rat LC 50: > 18,300 mg/m 3/1hr (TS: zeolite s A) (OECD SIDS)

Skin corrosion/irritation
Silver Copper Zeolite:
Skin Rat: Slight irritation. (Manufacturer Studies)

Silver Zeolite:
Skin Rat: No significant irritation (Manufacturer Studies)

Respiratory or skin sensitization
Silver Copper Zeolite:
Skin Guinea pig: Not sensitizing. (Manufacturer Studies)

Silver Zeolite:
Skin Rat: No significant irritation (Manufacturer Studies)

Germ cell mutagenicity
Silver Copper Zeolite:
In vitro Ames test: Non mutagenic. (Manufacturer Studies)

Silver Zeolite
Invitro Ames test: Non mutagenic.
In vivo Chromosome Aberration Assay: Silver Zinc Zeolite did not cause an increase in chromosomal aberrations at any time point in either male or female rats. (Manufacturer Studies)

Carcinogenicity
Not listed in IARC, NTP, or OSHA.

STOT-single exposure
No data available on product

STOT-repeated exposure
No data available on product

Aspiration hazard
No data available on product

SECTION 12: Ecological information

Toxicity
Ecotoxicity: No data available for this product.

Persistence and degradability
No data available on product

Bioaccumulative potential
No data available on product

Mobility in soil
No data available on product

Other adverse effects
Silver Copper Zeolite:
Effect of Material On Aquatic Life:
Pimephales promelas LC50 96 h 1.2 µg/L (Silver)
Daphnia magna LC50 48 h 0.22 µg/L (Silver)
Danio rerio NOEC 35 d 5.9 µg/L (Silver)
Ceriodaphnia dubia EC10 7 d 2.48 µg/L (Silver)
Nostoc musconum EC 10 15 d 0.16 µg/L (Silver)(ECHA)

Silver Zeolite:
Effect of Material On Aquatic Life: Oncorhynchus kisutch 96 h LC 50 820 µg/L (TS: Zinc chloride)
Daphnia magna 48 h LC 50 330 µg/L (TS: Zinc chloride)
Pseudokirchnerella subcapitata 72 h NO EC 5.4 µg/L (TS: Zinc chloride)
Oncorhynchus mykiss 30 d NO EC 39 µg/L (TS: Zinc chloride) (ECHA)

SECTION 13: Disposal considerations

Disposal of the product
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

SECTION 14: Transport information

DOT (US)
UN Number: Not regulated as hazardous material for transportation.
Proper Shipping Name: Not regulated as hazardous material for transportation.

IMDG
UN Number: UN3082
Class: 9
Packing Group: III
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (silver zeolite, silver copper zeolite)

IATA
UN Number: UN3082
Class: 9
Packing Group: III
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (silver zeolite, silver copper zeolite)

SECTION 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

SARA 313 Components
SARA 313 Listed, N740 Silver Compounds (8%), N100 Copper Compounds (12%)

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

New Jersey Right To Know Components
Propylene glycol
CAS number: 57-55-6

Pennsylvania Right To Know Components
Propylene glycol
CAS number: 57-55-6

SARA 302 Components
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

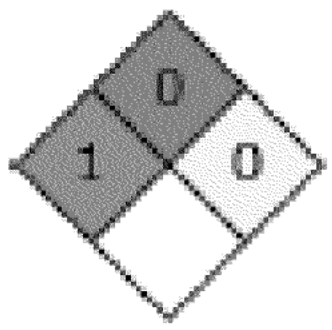
SARA 311/312 Hazards
No SARA Hazards

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

HMIS Rating

Agion® AM-B10G Slurry	
HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0
PERSONAL PROTECTION	X

NFPA Rating



SECTION 16: Other information

SDS Revision Date: January 01, 2020
SDS Revision Notes: Revision 6

Further Information/disclaimer
This SDS is valid for all countries in North America, South America, China, Taiwan, India, Japan, Bangladesh, Pakistan, Malaysia and Sri Lanka

AGION AM-B10G

TDS

TECHNICAL DATA SHEET

Agion® AM-B10G Slurry

Description: Agion® AM-B10G Slurry is a textile finishing agent that provides excellent antimicrobial performance to a wide variety of fabrics. It is a bluish tinted, aqueous based dispersion with type A zeolite powder containing ionic silver and copper. Agion® AM-B10G Slurry has an acrylic resin base so that no additional components are required. This formulation has been designed for use on fabric, garment and other similar applications. Agion AM-B10G is free of Zinc.

Product Specifications: The material is tested according to the test procedure included in the *"Inspection Standard"*, and must comply with the following specification values:

Parameter	Analytical Method	Unit	Specification Value
Copper Content	Atomic Absorption	Wt%	0.63-0.89
Silver Content	Atomic Absorption	Wt%	0.65-0.93
Particle Size Distribution	Laser Particle Analysis	µm	Mean less than 5
Percent Solids	Gravimetric Analysis	Wt%	35-50%

Typical Properties*:

Appearance	Bluish tint dispersion
Crystal Structure of Solids	Type A Zeolite
pH in water	6-9
(Weight per gallon, lb. @25°C	~9

**These items are provided as general information only. They are approximate values and are not considered part of the product specification.*

Storage and Handling:

Agion® AM-B10G Slurry should be stored in a tightly closed corrosion resistant containers to prevent evaporation of water and the introduction of contaminants that can adversely affect performance.

Do not store below 40° F (4°C) to protect from freezing or above 104°F (40°C) to maintain product quality.

Agion® AM-B10G Slurry should be thoroughly mixed prior to use to ensure a uniform dispersion, since settling will occur during prolonged storage. Particular attention should be paid to the bottom of the container to ensure homogeneous composition. In the case of large storage containers like totes, it is recommended to mix the tote with a suitable motor driven mixer, electric or air powered, at least once per day for approximately 30 minutes prior to use.

Do not use galvanized fittings or connections with AM-B10G. Only use stainless steel or PVC.

Further dilution of slurry with a suitable solvent may reduce the stability of the dispersion and continuous agitation during processing may be required to ensure uniform distribution.

Because Sciessent LLC does not control the use, processing or method of use to which others may put its antimicrobial agents, Sciessent does not guarantee the effectiveness or suitability of the agents for use in any particular process, application or article of manufacture. These agents are not suitable for or efficacious in all applications to which a user may desire to apply them. The user of any agent described in this Technical data Sheet should conduct their own tests to determine the suitability of the agent in their particular process, application or article of manufacture.

Sciessent LLC warrants that its products in the original, sealed containers will meet the product specifications for a period of three (3) months from the date of Shipment.

SCIESSENT DISLCAIMS ALL WARRANTIES, WHETHER EXPRESSED, IMPLIED, OR STATUTORY, INCLUDING THE WARRANTIES OF MECHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT SHALL SCIESSENT BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES HOWSOEVER ARISING. BUYER'S SOLE AND EXCLUSIVE REMEDY AGAINST SCIESSENT FOR ANY CAUSE OF ACTION ARISING OUT OF THE SALE OR USE OF ANY PRODUCT HEREIN DESCRIBED SHALL BE REPLACEMENT OF THE PRODUCT OR REFUND OF THE PURCHASE PRICE PAID FOR THE PRODUCT.

Sciessent

Silver Copper Type AC Label 3.27.15

Agion® Silver Copper Type AC

A preservative and bacteriostatic agent for use in the manufacture of polymer, plastic, latex products.
For commercial and industrial use only.

Active Ingredient:	
Silver	3.52 %
Copper	6.1 %
Other Ingredients	90.38 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Manufactured for:
Sciessent LLC
60 Audubon Rd
Wakefield, MA 01880

EPA Registration No. 71227-7-88165
EPA Establishment No. 88165-MA-001

Net Wt. XXXX

Lot No. XXXXXXXXX

Standard 51 Listed

Nonfood Compounds Program Listed PX

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For all uses listed*:

* Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System." Any incorporation of this product into an approved and listed food contact polymer must comply with the specific use conditions listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System," for such food contact polymer. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited.

* For applications involving direct or indirect food or human drinking water contact, Agion® Silver Copper Antimicrobial Type AC must be used with an FDA approved polymer or coating. Non-food and non-drinking water contact applications can use either FDA or non-FDA approved coatings.

* This product may be used for the following human drinking water contact uses:
  - water filter components and housing units
  - water bottle dispensers and components
  - water dispensers
  - ice machine trays
  - ice machine bins
  - ice machine water hoses
  - ice dispensers and other ice machine components
  - water bottles
  - cups
  - water storage vessels

* This product may be incorporated into food and water bowls, dishes and other containers used by domestic animals. Do not use for any food or drinking water applications involving non-domestic animals.

Agion® Silver Copper Antimicrobial Type AC. is an antimicrobial additive to be used by compounding into many polymeric materials. It is designed to be incorporated during the manufacturing process to impart antimicrobial activity to the manufactured products. *Agion® Silver Copper Antimicrobial Type AC* suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining, deterioration or corrosion only. No finished product incorporating *Agion® Silver Copper Antimicrobial Type AC* may make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the finished product which permits such claims. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

Types of Finished Products

Plastics - including films, sheets, slabs, and molded plastic parts

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.3% for bulk plastics. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer):

Packaging
Gaskets
general purpose containers
food and drink containers
food trays and covers
sponges
tubing
brush bristles (including personal care grooming items, toothbrushes), and cosmetic brushes
liners
non-woven fabrics,
plastic sheeting for construction and agricultural applications
appliances and equipment
kitchen and food processing utensils and Supplies
cutting boards
countertops
sinks
tiles
dishes, cups, bottles
conveyor belts
food processing equipment (including slicers formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders choppers, peelers and countertops)
beverage processing equipment (including mixers, transfer equipment, pumps, bottlers canners, dispensers and fermenters)
building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

Non-food contact uses only:

Automobile Parts
Mats
Waste containers
Mops
Plumbing supplies and fixtures
Siding for housing
Flooring
Insulation for wire and cable
Indoor and outdoor furniture
Spas, bathtubs, showers, filters and components thereof
Office equipment and supplies (including binders, filing and storage systems, pens, pencils, markers, printers, facsimile machines, desk accessories, computers, keyboards, mice scanners, and printers).
Medical devices, equipment and supplies
Shower curtains
Protective Covers
Brush handles
Vacuum cleaner bags
Drain pan liners
Kitchen and bathroom hardware
Floor coverings
Insulators
Plastic building materials
Garbage bags and garbage cans
Telephones, mobile devices, head phones, head sets and accessories
Cameras and Imaging equipment

Fibers – including cotton, rayon and synthetically derived fibers

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.5% for fibers. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating on an article):
Synthetic and Natural Fibers
napkins, tablecloths and wiping cloths
bags
brush bristles (including personal care grooming items, toothbrushes and cosmetic brushes)
filters
clothing apparel (including uniforms, outerwear, gloves, aprons, coats and shoes)
sponges
packaging (including bags, sacks, wraps, cushion and absorbent materials, and containers)
conveyor belts
kitchen, commercial and industrial wipes and fabrics

Non-food contact uses only:
Synthetic and Natural Fibers
Paper for gypsum board.
Paper, paperboard, composite building materials
Interior furnishings -
mattress cover pads and filling
pillow covers
sheets
blankets
fiberfill for quilts and pillows
curtains
draperies
carpet and carpet underlay
rugs
upholstery
mops
towels
wall covering fabrics
cushion pads
sleeping bags

Apparel –
umbrellas
outerwear
sportswear
sleepwear
stockings
socks and hosiery
caps
undergarments
inner liners for jackets
trim for outerwear and garments
medical devices, equipment and supplies

Transportation –
automotive and truck upholstery
carpeting
rear decks
trunk liners
convertible tops
interior liners

Industrial and Other Household Items -
artificial leather
filters
book covers
mops
cloth for sails
ropes
tents and other outdoor equipment
tarps
awnings
drain pan liners

Luggage -
Sports bags
Shoe bags
Sports bag accessories
Luggage
Duffel bags
Laundry bags
Cosmetic bags
Packing Organizers
Luggage Lining

Coatings, Films and Laminates

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for coatings. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder emulsion, starch, cellulosic, lacquer, thermoset, thermoplastic, thermal spray coatings including pre-dispersions and components thereof.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating, film or laminate on an article):
packaging
paper products (including wipes and tissues)
natural and synthetic fibers and fabrics
sinks
countertops
cutting boards
dishes
cookware
general purpose containers
kitchen, commercial and industrial utensils and supplies
collection and storage equipment (including conveyor belts, piping systems, silos, tanks and process vessels)
appliances and food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)
beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners and fermenters and dispensers)
building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

Non-food contact uses only:

Building Materials (including gypsum board, insulation, cellulose or fiberglass ceiling tile, and polymer flooring.)
Heating, Ventilation and Air Conditioning equipment and related materials (including insulation, ducts, heat exchangers, drain pans, air filters, air purifiers, diffusers, and parts and components thereof)[1]
Industrial equipment
Furniture
Automotive and vehicular parts
Packaging
Siding
Roofing
Shingles
Industrial equipment
Medical devices, equipment and supplies

Luggage -
Sports bags
Shoe bags
Sports bag accessories
Luggage
Duffel bags
Laundry bags
Cosmetic bags
Packing Organizers
Luggage Lining

Adhesives and Sealants

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for adhesives and sealants. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer incorporated into FDA-approved adhesives or sealants):
plumbing adhesives
pipe sealants and insulating materials
grout and joint compound for; countertops, building materials and components, and food and beverage related equipment

Non-food contact uses only:
Adhesives, joint compound and grout for gypsum board, ceramic tile, wood, paper, cardboard, rubber and plastic.
Medical devices, equipment and supplies

Miscellaneous Applications

The additive may be incorporated into the finished product at up to 5.0% by weight. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer or coating.

Interior paints and coatings
Stucco
Plaster
Leather
Medical devices, equipment and supplies

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Caution. Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling and before eating, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water of 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If inhaled	• Move person to fresh air. • If person if not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If swallowed	• Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

Storage and Disposal

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Do not store in areas accessible to children. Keep product dry and containers covered during storage; store below 130°F.

Container Disposal: Nonrefillable container. Do not reuse or refill inner plastic bag or outer steel can. **Inner Plastic Bag:** Completely empty plastic bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. **Outer Steel Can:** Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Pesticide Disposal: Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

Gerba

Anti-Viral properties of Agion

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ORIGINAL PAPER

Assessment of the Antiviral Properties of Zeolites Containing Metal Ions

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Abstract The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-$\log_{10}$ reduction within 24 h. It was also the most effective (>3.18-$\log_{10}$) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-$\log_{10}$ and >3.8-$\log_{10}$ reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.

Keywords Coronavirus · Calicivirus · Fomites · Antiviral · Copper · Silver

Introduction

By July of 2003, 8,098 probable cases of severe acute respiratory syndrome (SARS) resulting in 774 deaths had been reported to the World Health Organization (WHO) from 29 countries on five continents (Centers for Disease Control and Prevention 2003; World Health Organization 2004). A novel coronavirus, SARS coronavirus (SCoV) was isolated from patients (Ksiazek et al. 2003; Navas-Martin and Weiss 2004). Before the identification of SCoV, two coronaviruses were known to infect humans, strains 229E and OC43 (Navas-Martin and Weiss 2004). These cause mild, self-limiting, upper respiratory tract infections (Myint 1994) and belong to the Group I and Group II coronaviruses, respectively. SCoV possesses characteristics specific to all three coronavirus groups (Navas-Martin and Weiss 2004), but is not closely related to any (Poutanen et al. 2003). It is apparently an animal virus that recently adapted to cross the species barrier, allowing for human-to-human transmission (Anita et al. 2003).

Human norovirus (NoV) causes illness in an estimated 23 million people in the United States each year, resulting in 50,000 hospitalizations and 310 deaths (Mead et al. 1999). It has been suggested that NoV may be the leading cause of foodborne illness in the United States (Widdowson et al. 2005), responsible for approximately 66% of all cases with known etiologies (Mead et al. 1999) and at least 50% of all foodborne outbreaks of gastroenteritis (Centers for Disease Control and Prevention 2006). NoV was identified in 93% of nonbacterial gastroenteritis outbreaks by the Centers for Disease Control and Prevention (CDC) between 1997 and 2000 in the United States (Fankhauser et al. 2002). Similarly, surveillance by the Foodborne Viruses in Europe network found that NoV was responsible for greater than 85% of all nonbacterial gastroenteritis outbreaks from 1995 to 2000 (Lopman et al. 2003).

Nonenveloped viruses are typically more resistant to environmental conditions and the action of antimicrobials

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than enveloped viruses (Watanabe et al. 1989; Barker et al. 2001). Feline calicivirus has been found to persist for up to 28 days in a dry environment at room temperature (Doultree et al. 1999). Also, in a study by Smid et al. (1991), rabbit hemorrhagic disease virus (also a calicivirus) survived for at least 105 days in a dried state at room temperature. Viruses that cause symptoms such as vomiting or diarrhea are likely to contaminate the environment. In one study, 607 of 680 (89%) norovirus outbreaks were linked to person-to-person transmission (Evans et al. 1998) that included poor hand hygiene as well as surface-to-surface transmission (Barker et al. 2001). Also, successive outbreaks of norovirus infections in passengers on cruise ships on separate trips have strongly implicated environmental contamination (Barker et al. 2001). Enveloped viruses are typically less stable in the environment, yet the SCoV is able to survive on fomites for up to 96 h (Duan et al. 2003). The transmission of SCoV is believed to be multifactorial, with evidence from previous outbreaks suggestive of at least some role for contaminated fomites in the transmission of the virus (Dowell et al. 2004; Chu et al. 2005).

Zeolite (sodium aluminosilicate) powders (AgION Technologies, Wakefield, MA, USA) form porous crystals. Metal ions may reside within these pores and zeolites can act as ion exchangers, exchanging metal ions for other cations in the environment. Although the effect of metal-zeolites has been documented in numerous studies with bacteria (Bright et al. 2002; Takai et al. 2002; Cowan et al. 2003; Rusin et al. 2003; Kwakye-Awuah et al. 2008), the use of zeolite powders containing heavy metal ions to reduce coronaviruses and caliciviruses has not been previously reported. This paper describes the antiviral effect of suspensions of zeolite powders amended with silver (Ag), copper (Cu), and zinc (Zn) ions in phosphate-buffered saline against human coronavirus 229E and feline infectious peritonitis virus (FIPV; feline coronavirus). This report also includes tests of the survival of human coronavirus 229E, FIPV, and feline calicivirus on the surfaces of plastics with zeolite containing Ag and Cu ions incorporated into the plastic.

Human coronavirus 229E and FIPV were employed in this study as surrogates for other coronaviruses. Feline calicivirus was also included as a surrogate for NoV. There is currently no practical method for propagating human NoV in cell culture monolayers. Feline calicivirus, on the other hand, grows readily in cell culture. It is in the same family as human NoV and is commonly used as a NoV surrogate in experiments (Slomka and Appleton 1998; Clay et al. 2006) because of its biochemical and genetic similarities to NoV (Jiang et al. 1993).

Materials and Methods

Virus Preparation

Human coronavirus strain 229E (ATCC #VR-740) was obtained from the American Type Culture Collection (ATCC, Manassas, VA, USA). It was maintained on MRC-5 (fetal human lung fibroblast, ATCC #CCL-171) cell line monolayers with minimal essential medium (MEM, modified with Earle's salts, Irvine Scientific, Santa Ana, CA, USA) containing 2% fetal bovine serum (FBS, Hyclone, Logan, UT, USA) at an incubation temperature of 35°C with 5% CO_2. Coronavirus 229E replicates better at this temperature than at 37°C. Feline infectious peritonitis virus (FIPV; ATCC #VR-990) and feline calicivirus strain F-9 (ATCC #VR-782) were maintained in the same manner on CRFK (Crandell Reese feline kidney, ATCC #CCL-94) cell line monolayers.

Viruses were purified by centrifugation (750×*g*) to remove cell debris followed by polyethylene glycol (9% PEG, 0.5 mol/l NaCl) precipitation. Viral titrations were performed using the Reed-Muench method (Payment and Trudel 1993) to determine the tissue culture infectious dose that affected 50% of the cultures ($TCID_{50}$).

Metal-Zeolite Powders in Suspension

Coronavirus strains 229E and FIPV were added to Erlenmeyer flasks containing 30.0 ml of phosphate buffered saline (PBS, pH 7.4; Sigma-Aldrich, St. Louis, MO, USA) with 10.0 mg of suspended zeolite test powder [either unamended powder, 20.0% Ag (w/w), 3.5% Ag/6.5% Cu, or 0.6% Ag/14% Zn/80% ZnO] (AgION Technologies, Wakefield, MA, USA). Positive control flasks without zeolite powder were also included. All experiments were performed in duplicate.

The positive control flasks (without zeolite powders) were sampled immediately ($t = 0$ h) by removing 1.0 ml from each flask and placing it into 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA). The 2.0 ml volumes were mixed thoroughly and placed into 4.0 ml of PBS (pH 7.4). All test flasks were then placed on an orbital shaker (200 rpm) at room temperature (23°C) and were sampled at 1, 4, and 24 h in the manner described previously. All samples were frozen in 1.0 ml aliquots at −80°C. Frozen aliquots were subsequently assayed using the Reed-Muench $TCID_{50}$ method as before (Payment and Trudel 1993).

Plastics with Incorporated Metal-Zeolites

Plastic coupons (5 cm by 5 cm) with either 5 or 10% (w/w) zeolite (containing 3.5% Ag and 6.5% Cu ions) incorporated

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (w/w), but with differing amounts [5 or 10% w/w] of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23°C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

Statistical Analysis

A Student's *t* test was used to compare the viral counts recovered from the flasks containing test powder suspensions and test plastic coupons to those recovered from the positive controls.

Results

Metal-Zeolite Powders in Suspension

Amended zeolite powder suspensions were compared to determine which heavy metal combinations demonstrated the greatest activity against human coronavirus 229E. Unamended powder was used as a control to evaluate the effect of adsorption. The effect of Cu alone was undetermined. The results of the suspension tests are presented in Table 1. The results from the flasks containing zeolite control powder indicate that removal of virus was not due to adsorption by zeolite particles. Of the powder suspensions tested, the 3.5% Ag/6.5% Cu ion combination was the most efficacious, yielding a 1.08-log_{10} reduction of 229E after 1 h, a 2.06-log_{10} reduction after 4 h, and a >5.13-log_{10} reduction after 24 h of exposure. The greatest reductions observed for the other amended powders were following 24 h of exposure; nevertheless, the reductions at 24 h were not significantly greater ($P = 0.274$) than those after 4 h of exposure.

The 3.5% Ag/6.5% Cu combination was also effective (>3.18-log_{10} reduction) against FIPV within 4 h; however, neither of the other formulations was effective against FIPV, even after 24 h of exposure.

Plastics with Incorporated Metal-Zeolites

The results for the virus survival on the plastics with incorporated Ag/Cu-zeolite are shown in Table 2. Significant reductions were observed for coronavirus 229E on the Ag/Cu-zeolite plastic coupons after 24 h of exposure with a 1.84-log_{10} and a 1.77-log_{10} reduction achieved on the 5% and 10% (w/w) zeolite coupons, respectively. The

Table 1 Log_{10} reduction of coronavirus after exposure to zeolite test powders amended with heavy metals

Virus	Time (h)	Positive control[a]	Zeolite control[b]	Amended zeolite powder (w/w)		
				3.5% Ag 6.5% Cu	20% Ag	0.6% Ag 14% Zn 80% ZnO
229E (human)	1	0.00 ± 0.00	0.00 ± 0.24	1.08* ± 0.07	0.43* ± 0.09	0.50 ± 0.24
	4	0.20 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.43
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.6×10^5 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

Table 2 Log_{10} reduction of viruses on plastic coupons impregnated (5% or 10%) with zeolite powder (containing 6.5% copper, 3.5% silver ions)

Virus	Time (h)	Positive control[a]	5% Zeolite (w/w)	10% Zeolite (w/w)
Coronavirus 229E	1	0.22 ± 0.51	0.93 ± 0.05	0.80 ± 0.00
	4	0.90 ± 0.61	0.52 ± 0.47	0.44 ± 0.24
	24	0.67 ± 0.61	1.84* ± 0.20	1.77* ± 0.24
Feline calicivirus	1	0.04 ± 0.03	0.25* ± 0.06	0.67* ± 0.14
	4	0.17 ± 0.08	0.64* ± 0.19	0.96 ± 1.45
	24	0.40 ± 0.32	3.84 ± 1.02	5.05* ± 0.21

The experiment was conducted in triplicate at room temperature. The original titer was 4.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.0×10^6 PFU/ml for feline calicivirus. The ± indicates the standard deviation for the triplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Plastic coupons without zeolite

reductions for feline calicivirus were greater, including a 3.84-log_{10} reduction on the 5% Ag/Cu-zeolite coupons and a 5.05-log_{10} reduction on the 10% Ag/Cu-zeolite coupons after 24 h.

Discussion

To date, there have been no detailed studies of the interaction between heavy metals and viruses. Viruses that contain sulfhydryl termini may bind silver, interfering with viral replication (Davies and Etris 1997). Silver may also modify the adsorption of viruses to host cells (Tzagoloff and Pratt 1964). Thurman and Gerba (1989) suggested that viral inactivation might not require a metabolic process. For instance, the virus may be immobilized to a surface, the host-cell receptors may be blocked, or the nucleic acid within the viral capsid may be inactivated.

Copper is toxic to most microorganisms at higher concentrations, possibly due to the blocking of functional groups on proteins and the inactivation of enzymes (Saunder et al. 2004). Zinc oxide produces an active oxygen species at its surface that has a similar oxidative effect to hydrogen peroxide when it dissociates. This may damage the viral capsid and allow more metal ions inside the virus.

Unlike the respiratory disease caused by coronavirus 229E, FIPV causes gastrointestinal symptoms. The fact that Ag/Cu zeolite is effective against two substantially different coronaviruses suggests that it may also be effective in reducing the SCoV which causes severe respiratory disease, but which may also have a gastrointestinal component and is shed in the feces for greater than 10 weeks (Leung et al. 2003). The Ag/Cu zeolite was also effective against the nonenveloped feline calicivirus whose physical properties differ greatly from the enveloped coronaviruses.

Zeolite powders containing antiviral heavy metals have many potential applications. They may be added to materials such as plastics, paints, and synthetic fabrics (Quintavalla and Vicini 2002; Takai et al. 2002), and may be bonded to surfaces such as stainless steel (Bright et al. 2002; Cowan et al. 2003; Rusin et al. 2003). The effectiveness of the Ag/Cu zeolite against substantially different viruses appears promising for its potential use in applications to reduce environmental contamination of fomites by viral pathogens and thus the spread of diseases. Additional tests utilizing zeolites containing copper ions alone or in combination with various metals against other disparate viruses are needed.

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References

Antia, R., Regoes, R. R., Koella, J. C., & Bergstrom, C. T. (2003). The role of evolution in the emergence of infectious diseases. *Nature, 426*, 658–661.

Barker, J., Stevens, D., & Bloomfield, S. F. (2001). Spread and prevention of some common viral infections in community facilities and domestic homes. *Journal of Applied Microbiology, 91*, 7–21.

Bidawid, S., Malik, N., Adegunrin, O., Sattar, S. S., & Farber, J. M. (2003). A feline kidney cell line-based plaque assay for feline calicivirus, a surrogate for Norwalk virus. *Journal of Virological Methods, 107*, 163–167.

Bright, K. R., Gerba, C. P., & Rusin, P. A. (2002). Rapid reduction of *Staphylococcus aureus* populations on stainless steel surfaces by zeolite ceramic coatings containing silver and zinc ions. *The Journal of Hospital Infection, 52*, 307–309.

Centers for Disease Control and Prevention. (2003). Revised U.S. surveillance case definition for severe acute respiratory syndrome (SARS) and update on SARS cases–United States and Worldwide, December 2003. *Morbidity and Mortality Weekly Report, 52*, 1202–1206.

Centers for Disease Control and Prevention. (2006). Norovirus: Technical fact sheet. http://www.cdc.gov/ncidod/dvrd/revb/gastro/downloads/noro-factsheet.pdf. Accessed 22 September 2008.

Chu, C. M., Cheng, V. C. C., Hung, I. F. N., Chan, K. S., Tang, B. S. F., Tsang, T. H. F., et al. (2005). Viral load distribution in SARS outbreak. *Emerging Infectious Diseases, 11*, 1882–1886.

Clay, S., Maherchandani, S., Malik, Y. S., & Goyal, S. M. (2006). Survival on uncommon fomites of feline calicivirus, a surrogate of noroviruses. *American Journal of Infection Control, 34*, 41–43.

Cowan, M. M., Abshire, K. Z., Houk, S. L., & Evans, S. M. (2003). Antimicrobial efficacy of a silver-zeolite matrix coating on stainless steel. *Journal of Industrial Microbiology & Biotechnology, 30*, 102–106.

Davies, R. L., & Finn, S. F. (1997). Development and functions of silver in water-purification and disease-control. *Catalysis Today, 36*, 107–114.

Doultree, J. C., Druce, J. D., Birch, C. J., Bowden, D. S., & Marshall, J. A. (1999). Inactivation of feline calicivirus, a Norwalk virus surrogate. *The Journal of Hospital Infection, 41*, 51–57.

Dowell, S. F., Simmerman, J. M., Erdman, D. D., Wu, J. S. J., Chaovavanich, A., Javadi, M., et al. (2004). Severe acute respiratory syndrome coronavirus on hospital surfaces. *Clinical Infectious Diseases, 39*, 652–657.

Duan, S. M., Zhao, X. S., Wen, R. F., Huang, J. J., Pi, G. H., Zhang, S. X., et al. (2003). Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation. *Biomedical and Environmental Sciences, 16*, 246–255.

Evans, H. S., Madden, P., Douglas, C., Adak, G. K., O'Brien, S. J., Djuretic, T., et al. (1998). General outbreaks of infectious intestinal disease in England and Wales: 1995 and 1996. *Communicable Disease and Public Health, 1*, 165–171.

Fankhauser, R. L., Monroe, S. S., Noel, J. S., Ando, T. A., & Glass, R. I. (2002). Epidemiologic and molecular trends of Norwalk-like viruses associated with outbreaks of gastroenteritis in the United States. *The Journal of Infectious Diseases, 186*, 1–7.

Faundez, G., Troncoso, M., Navarrete, P., & Figueroa, G. (2004). Antimicrobial activity of copper surfaces against suspensions of *Salmonella enterica* and *Campylobacter jejuni*. *BMC Microbiology, 4*, 19.

Jiang, X., Wang, M., Wang, K., & Estes, M. K. (1993). Sequence and genomic organization of Norwalk virus. *Virology, 195*, 51–61.

Kuiken, T. G., Fouchier, R., Goldsmith, C. S., Zaki, S. R., Peret, T., Emery, S., et al. (2003). A novel coronavirus associated with severe acute respiratory syndrome. *The New England Journal of Medicine, 348*, 1953–1966.

Kwakye-Awuah, B., Williams, C., Kenward, M. A., & Radecka, I. (2008). Antimicrobial action and efficiency of silver-loaded zeolite X. *Journal of Applied Microbiology, 104*, 1516–1524.

Leung, W. K., To, K. F., Chan, P. K., Chan, H. L., Wu, A. K., Lee, N., et al. (2003). Enteric involvement of severe acute respiratory syndrome-associated coronavirus infection. *Gastroenterology, 125*, 1011–1017.

Lopman, B. A., Reacher, M. H., van Duijnhoven, Y., Hanon, F. X., Brown, D., & Koopmans, M. (2003). Viral gastroenteritis outbreaks in Europe, 1995–2000. *Emerging Infectious Diseases, 9*, 90–96.

Mead, P. S., Slutsker, L., Dietz, V., McCaig, L. F., Bresee, J. S., Shapiro, C., et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases, 5*, 607–625.

Myint, S. H. (1994). Human coronaviruses—A brief review. *Reviews in Medical Virology, 4*, 35–46.

Navas-Martín, S., & Weiss, S. (2004). Coronavirus replication and pathogenesis: Implications for the recent outbreak of severe acute respiratory syndrome (SARS), and the challenge for vaccine development. *Journal of Neurovirology, 10*, 75–85.

Payment, P., & Trudel, M. (1993). Isolation and identification of viruses. In P. Payment & M. Trudel (Eds.), *Methods and techniques in virology* (pp. 32–33). New York: Marcel Dekker.

Poutanen, S. M., Low, D. E., Henry, B., Finkelstein, S., Rose, D., Green, K., et al. (2003). Identification of severe acute respiratory syndrome in Canada. *The New England Journal of Medicine, 348*, 1995–2005.

Quintavalla, S., & Vicini, L. (2002). Antimicrobial food packaging in meat industry. *Meat Science, 62*, 373–380.

Rusin, P., Bright, K., & Gerba, C. (2003). Rapid reduction of *Legionella pneumophila* on stainless steel with zeolite coatings containing silver and zinc ions. *Letters in Applied Microbiology, 36*, 69–72.

Slomka, M. J., & Appleton, H. (1998). Feline calicivirus as a model system for heat inactivation studies of small round structured viruses in shellfish. *Epidemiology and Infection, 121*, 401–407.

Smid, B., Valicek, L., Rodak, L., Stepanek, J., & Jurak, E. (1991). Rabbit haemorrhagic disease: An investigation of some properties of the virus and evaluation of an inactivated vaccine. *Veterinary Microbiology, 26*, 77–85.

Takai, K. T., Ohtsuka, T., Sendai, Y., Nakao, M., Yamamoto, K., Matsuoka-Iunji, J., et al. (2002). Antibacterial properties of antimicrobial-finished textile products. *Microbiology and Immunology, 46*, 75–81.

Thurman, R. B., & Gerba, C. P. (1989). The molecular mechanisms of copper and silver ion disinfection of bacteria and viruses. *CRC Critical Reviews in Environmental Control, 18*, 295–315.

Tzagoloff, H., & Pratt, D. (1964). The initial steps in infection with coliphage M13. *Virology, 24*, 372–380.

Watanabe, Y., Miyata, H., & Sato, H. (1980). Inactivation of laboratory animal RNA-viruses by physicochemical treatment. *Jikken Dobutsu, 38*, 305–311.

Widdowson, M. A., Sulka, A., Bulens, S. N., Beard, R. S., Chaves, S. S., Hammond, R., et al. (2005). Norovirus and foodborne disease, United States, 1991–2000. *Emerging Infectious Diseases, 11*, 95–102.

World Health Organization. (2004). *WHO guidelines for the global surveillance of severe acute respiratory syndrome (SARS) Updated recommendations October 2004*. New Delhi, India: Department of Communicable Disease Surveillance and Response, Regional Office for South-East Asia, World Health Organization.

Sciessent

Coronavirus White Paper

sciessent

Agion Antimicrobial Efficacy Against Coronavirus is Tested and Published

The technology is deployed in the EU, Canada and United States in FDA cleared N95 respirator

February 10, 2020

The novel coronavirus (nCoV) outbreak in China has prompted several inquiries to Sciessent regarding the ability of Agion Antimicrobial to inactivate viruses. This white paper summarizes some university and government research previously completed on the antiviral properties of Agion.

Initial Research

The first half of the 2000's was marked by viral outbreaks that included H5N1 avian influenza, norovirus on cruise ships and the SARS coronavirus. Sciessent (formerly Agion Technologies) engaged with university researchers, industry partners and government organizations to investigate the ability of Agion to inactivate viruses. At the time the Chinese Center for Disease Control was looking for approaches to control the coronavirus and evaluated the Agion powder for efficacy. Around the same time Sciessent began working with Prof. Charles Gerba at the University of Arizona and to evaluate antiviral properties of Agion.

A Note on Terminology

Viruses are not living organisms; they must enter a living cell to multiply. Therefore, antiviral agents are said to "inactivate" viruses, not "kill" them.

Test Results

Chinese CDC (2003)

- Complete inactivation of SARS coronavirus in 2 hours
- *VERO E6 cell substrate, using virus CPE method*

University of Arizona (2004)

- 90% reduction of human coronavirus 229E in 1 hour
- 99% reduction of human coronavirus 229E in 2 hours
- 99.999% reduction of human coronavirus 229E in 24 hours
- *TCID50 technique, monitoring MRC-5 cell monolayers for cytopathic effects*

Chinese Academy of Agricultural Sciences (2006)

- 99% reduction of H5N1 avian influenza in 10 minutes
- *Klein-Defors suspension eradication test*

Published Research

A portion of the above results were published by Professor Gerba and his team in the peer-reviewed scientific journal *Food and Environmental Virology*:

> Assessment of the Antiviral Properties of Zeolites Containing Metal Ions.
> Food Environ Virol (2009) 1:37–41
>
> Abstract
>
> The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-log10 reduction within 24 h. It was also the most effective (>3.18-log10) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-log10 and >3.8-log10 reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.
>
> *Note: Springer Nature is making Coronavirus research free, including the above article.*

Agion in Polyester Fiber

During this time Sciessent worked with Foss Manufacturing (now Foss Performance Materials) to develop a polyester fiber with Agion embedded into the fiber itself. The fiber, named Fosshield, was incorporated into N95 respirator media as an approach to limit contamination of the respirator by the wearer or those around them. Further antiviral efficacy testing was performed on the respirator media construction.

N95 Respirator Media Test Results

- 99.98% reduction of coronavirus in 4 hours*
- 99.6% reduction of adenovirus in 1 hour*
- 99.999% reduction of haemophilus influenzae in 1 hour*
- 99.8% reduction of feline calicivirus (norovirus surrogate) in 4 hours*

**Results based on testing of samples containing Agion Antimicrobial*

Once proven, the media was manufactured by Nexera Medical into an N95 respirator, which underwent extensive testing and was submitted to the FDA in 2009. The Nexera Spectrashield surgical respirator was cleared by NIOSH and received a 510(k) from the Food and Drug Administration in 2011 and has since been cleared in Canada and the European Union.

Approved claims for the European Union:

http://www.nexeramed.com/nfiles/news_110711_1.php

Approved claims for Canada:

http://www.nexeramed.com/cfiles/regulatory.php?region=CA

Application Options

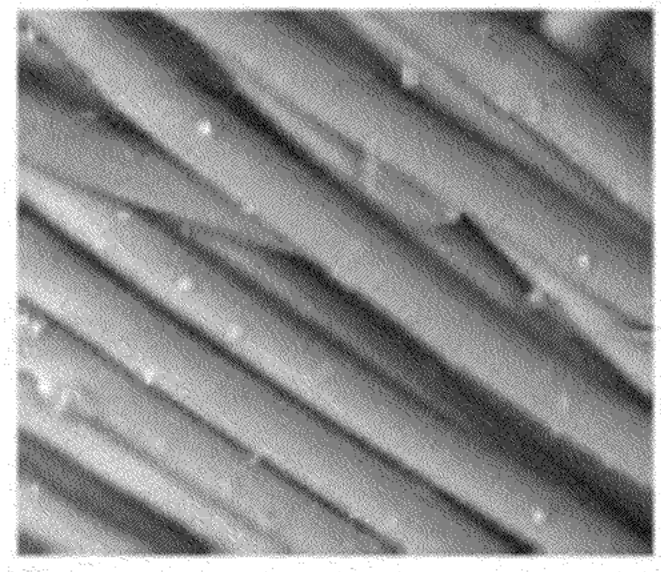
Agion is a versatile material that can be mixed into coatings, compounded into plastics, and applied to textiles using several processes:

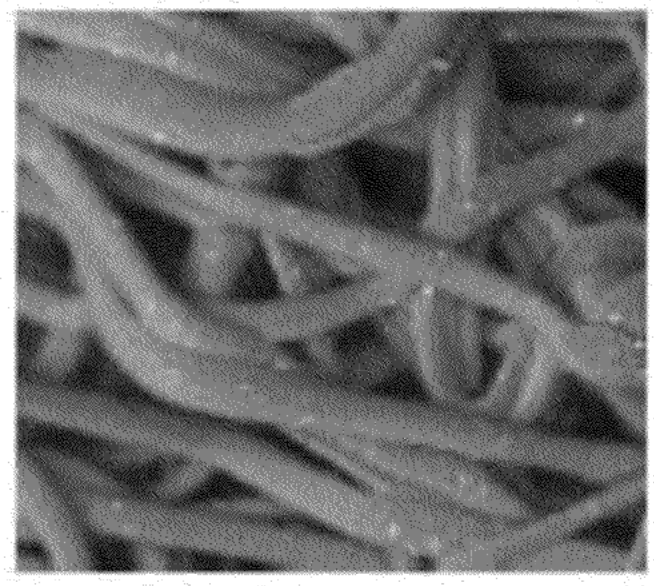
Topical – Fastest and most versatile

- Pad/Dry/Cure
- Exhaust
- Dip/Extract
- Yarn Package

Embedded

- Filament or staple fiber spinning
- Melt blown nonwoven
- Spunbond nonwoven





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Fosshield: http://www.fosspm.com/technology/fosshield.php

The Agion® Antimicrobial is presently registered by the United States Environmental Protection Agency as a preservative and bacteriostatic agent for use in treated articles under 40 CFR 152.25a. The information presented herein is not intended to support or endorse public health claims for treated articles. The Agion Antimicrobial is also used in medical devices under the Food and Drug Administration in the US; those medical device claims are based on safety and efficacy testing and are limited to those approved by FDA. In the EU, the Agion Antimicrobial is used in medical devices under the Medical Device Directive; those medical device claims are based on safety and efficacy testing and are limited to those approved by the designated Competent Authorities and/or Notified Bodies

Gerba

Assessment of the Antiviral properties of Zeolites Containing Metal Ions

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ORIGINAL PAPER

Assessment of the Antiviral Properties of Zeolites Containing Metal Ions

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Abstract The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-$\log_{10}$ reduction within 24 h. It was also the most effective (>3.18-$\log_{10}$) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-$\log_{10}$ and >3.8-$\log_{10}$ reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.

Keywords Coronavirus · Calicivirus · Fomites · Antiviral · Copper · Silver

Introduction

By July of 2003, 8,098 probable cases of severe acute respiratory syndrome (SARS) resulting in 774 deaths had been reported to the World Health Organization (WHO) from 29 countries on five continents (Centers for Disease Control and Prevention 2003; World Health Organization 2004). A novel coronavirus, SARS coronavirus (SCoV) was isolated from patients (Ksiazek et al. 2003; Navas-Martin and Weiss 2004). Before the identification of SCoV, two coronaviruses were known to infect humans, strains 229E and OC43 (Navas-Martin and Weiss 2004). These cause mild, self-limiting, upper respiratory tract infections (Myint 1994) and belong to the Group I and Group II coronaviruses, respectively. SCoV possesses characteristics specific to all three coronavirus groups (Navas-Martín and Weiss 2004), but is not closely related to any (Poutanen et al. 2003). It is apparently an animal virus that recently adapted to cross the species barrier, allowing for human-to-human transmission (Anfia et al. 2003).

Human norovirus (NoV) causes illness in an estimated 23 million people in the United States each year, resulting in 50,000 hospitalizations and 310 deaths (Mead et al. 1999). It has been suggested that NoV may be the leading cause of foodborne illness in the United States (Widdowson et al. 2005), responsible for approximately 66% of all cases with known etiologies (Mead et al. 1999) and at least 50% of all foodborne outbreaks of gastroenteritis (Centers for Disease Control and Prevention 2006). NoV was identified in 93% of nonbacterial gastroenteritis outbreaks by the Centers for Disease Control and Prevention (CDC) between 1997 and 2000 in the United States (Fankhauser et al. 2002). Similarly, surveillance by the Foodborne Viruses in Europe network found that NoV was responsible for greater than 85% of all nonbacterial gastroenteritis outbreaks from 1995 to 2000 (Lopman et al. 2003).

Nonenveloped viruses are typically more resistant to environmental conditions and the action of antimicrobials

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than enveloped viruses (Watanabe et al. 1989; Barker et al. 2001). Feline calicivirus has been found to persist for up to 28 days in a dry environment at room temperature (Doultree et al. 1999). Also, in a study by Smid et al. (1991), rabbit hemorrhagic disease virus (also a calicivirus) survived for at least 105 days in a dried state at room temperature. Viruses that cause symptoms such as vomiting or diarrhea are likely to contaminate the environment. In one study, 607 of 680 (89%) norovirus outbreaks were linked to person-to-person transmission (Evans et al. 1998) that included poor hand hygiene as well as surface-to-surface transmission (Barker et al. 2001). Also, successive outbreaks of norovirus infections in passengers on cruise ships on separate trips have strongly implicated environmental contamination (Barker et al. 2001). Enveloped viruses are typically less stable in the environment, yet the SCoV is able to survive on fomites for up to 96 h (Duan et al. 2003). The transmission of SCoV is believed to be multifactorial, with evidence from previous outbreaks suggestive of at least some role for contaminated fomites in the transmission of the virus (Dowell et al. 2004; Chu et al. 2005).

Zeolite (sodium aluminosilicate) powders (AgION Technologies, Wakefield, MA, USA) form porous crystals. Metal ions may reside within these pores and zeolites can act as ion exchangers, exchanging metal ions for other cations in the environment. Although the effect of metal-zeolites has been documented in numerous studies with bacteria (Bright et al. 2002; Takai et al. 2002; Cowan et al. 2003; Rusin et al. 2003; Kwakye-Awuah et al. 2008), the use of zeolite powders containing heavy metal ions to reduce coronaviruses and caliciviruses has not been previously reported. This paper describes the antiviral effect of suspensions of zeolite powders amended with silver (Ag), copper (Cu), and zinc (Zn) ions in phosphate-buffered saline against human coronavirus 229E and feline infectious peritonitis virus (FIPV; feline coronavirus). This report also includes tests of the survival of human coronavirus 229E, FIPV, and feline calicivirus on the surfaces of plastics with zeolite containing Ag and Cu ions incorporated into the plastic.

Human coronavirus 229E and FIPV were employed in this study as surrogates for other coronaviruses. Feline calicivirus was also included as a surrogate for NoV. There is currently no practical method for propagating human NoV in cell culture monolayers. Feline calicivirus, on the other hand, grows readily in cell culture. It is in the same family as human NoV and is commonly used as a NoV surrogate in experiments (Slomka and Appleton 1998; Clay et al. 2006) because of its biochemical and genetic similarities to NoV (Jiang et al. 1993).

Materials and Methods

Virus Preparation

Human coronavirus strain 229E (ATCC #VR-740) was obtained from the American Type Culture Collection (ATCC, Manassas, VA, USA). It was maintained on MRC-5 (fetal human lung fibroblast, ATCC #CCL-171) cell line monolayers with minimal essential medium (MEM, modified with Earle's salts, Irvine Scientific, Santa Ana, CA, USA) containing 2% fetal bovine serum (FBS, Hyclone, Logan, UT, USA) at an incubation temperature of 35°C with 5% CO_2. Coronavirus 229E replicates better at this temperature than at 37°C. Feline infectious peritonitis virus (FIPV; ATCC #VR-990) and feline calicivirus strain F-9 (ATCC #VR-782) were maintained in the same manner on CRFK (Crandell Reese feline kidney, ATCC #CCL-94) cell line monolayers.

Viruses were purified by centrifugation (750 ×*g*) to remove cell debris followed by polyethylene glycol (9% PEG, 0.5 mol/l NaCl) precipitation. Viral titrations were performed using the Reed-Muench method (Payment and Trudel 1993) to determine the tissue culture infectious dose that affected 50% of the cultures ($TCID_{50}$).

Metal-Zeolite Powders in Suspension

Coronavirus strains 229E and FIPV were added to Erlenmeyer flasks containing 30.0 ml of phosphate buffered saline (PBS, pH 7.4; Sigma-Aldrich, St. Louis, MO, USA) with 10.0 mg of suspended zeolite test powder [either unamended powder, 20.0% Ag (w/w), 3.5% Ag/6.5% Cu, or 0.6% Ag/14% Zn/80% ZnO] (AgION Technologies, Wakefield, MA, USA). Positive control flasks without zeolite powder were also included. All experiments were performed in duplicate.

The positive control flasks (without zeolite powders) were sampled immediately ($t = 0$ h) by removing 1.0 ml from each flask and placing it into 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA). The 2.0 ml volumes were mixed thoroughly and placed into 4.0 ml of PBS (pH 7.4). All test flasks were then placed on an orbital shaker (200 rpm) at room temperature (23°C) and were sampled at 1, 4, and 24 h in the manner described previously. All samples were frozen in 1.0 ml aliquots at −80°C. Frozen aliquots were subsequently assayed using the Reed-Muench $TCID_{50}$ method as before (Payment and Trudel 1993).

Plastics with Incorporated Metal-Zeolites

Plastic coupons (5 cm by 5 cm) with either 5 or 10% (w/w) zeolite (containing 3.5% Ag and 6.5% Cu ions) incorporated

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (w/w), but with differing amounts [5 or 10% w/w] of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23 °C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

Statistical Analysis

A Student's *t* test was used to compare the viral counts recovered from the flasks containing test powder suspensions and test plastic coupons to those recovered from the positive controls.

Results

Metal-Zeolite Powders in Suspension

Amended zeolite powder suspensions were compared to determine which heavy metal combinations demonstrated the greatest activity against human coronavirus 229E. Unamended powder was used as a control to evaluate the effect of adsorption. The effect of Cu alone was undetermined. The results of the suspension tests are presented in Table 1. The results from the flasks containing zeolite control powder indicate that removal of virus was not due to adsorption by zeolite particles. Of the powder suspensions tested, the 3.5% Ag/6.5% Cu ion combination was the most efficacious, yielding a 1.08-$\log_{10}$ reduction of 229E after 1 h, a 2.06-$\log_{10}$ reduction after 4 h, and a >5.13-$\log_{10}$ reduction after 24 h of exposure. The greatest reductions observed for the other amended powders were following 24 h of exposure; nevertheless, the reductions at 24 h were not significantly greater ($P = 0.274$) than those after 4 h of exposure.

The 3.5% Ag/6.5% Cu combination was also effective (>3.18-$\log_{10}$ reduction) against FIPV within 4 h; however, neither of the other formulations was effective against FIPV, even after 24 h of exposure.

Plastics with Incorporated Metal-Zeolites

The results for the virus survival on the plastics with incorporated Ag/Cu-zeolite are shown in Table 2. Significant reductions were observed for coronavirus 229E on the Ag/Cu-zeolite plastic coupons after 24 h of exposure with a 1.84-$\log_{10}$ and a 1.77-$\log_{10}$ reduction achieved on the 5% and 10% (wt/wt) zeolite coupons, respectively. The

Table 1 Log_{10} reduction of coronaviruses after exposure to zeolite test powders amended with heavy metals

Virus	Time (h)	Positive control[a]	Zeolite control[b]	Amended zeolite powder (w/w)		
				3.5% Ag 6.5% Cu	20% Ag	0.6% Ag 14% Zn 80% ZnO
229E (human)	1	0.00 ± 0.00	0.00 ± 0.24	1.08* ± 0.07	0.43* ± 0.09	0.30 ± 0.24
	4	0.70 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.48
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^6 $TCID_{50}$/ml for human coronavirus and 5.6×10^5 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (*w/w*), but with differing amounts [5 or 10% w/w] of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23 °C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

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	4	0.70 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.48
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^6 $TCID_{50}$/ml for human coronavirus and 5.6×10^5 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

Table 2 Log_{10} reduction of viruses on plastic coupons impregnated (5% or 10%) with zeolite powder (containing 6.5% copper, 3.5% silver ions)

Virus	Time (h)	Positive control[a]	5% Zeolite (w/w)	10% Zeolite (w/w)
Coronavirus 229E	1	0.22 ± 0.51	0.93 ± 0.05	0.80 ± 0.00
	4	0.50 ± 0.61	0.52 ± 0.47	0.44 ± 0.34
	24	0.67 ± 0.61	1.84* ± 0.30	1.77* ± 0.34
Feline calicivirus	1	0.04 ± 0.09	0.25* ± 0.06	0.67* ± 0.14
	4	0.17 ± 0.08	0.64* ± 0.19	0.96 ± 1.45
	24	0.40 ± 0.32	3.84 ± 1.02	5.05* ± 0.21

The experiment was conducted in triplicate at room temperature. The original titer was 4.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.0×10^6 PFU/ml for feline calicivirus. The ± indicates the standard deviation for the triplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Plastic coupons without zeolite

reductions for feline calicivirus were greater, including a 3.84-$\log_{10}$ reduction on the 5% Ag/Cu-zeolite coupons and a 5.05-$\log_{10}$ reduction on the 10% Ag/Cu-zeolite coupons after 24 h.

Discussion

To date, there have been no detailed studies of the interaction between heavy metals and viruses. Viruses that contain sulfhydryl termini may bind silver, interfering with viral replication (Davies and Etris 1997). Silver may also modify the adsorption of viruses to host cells (Tzagoloff and Pratt 1964). Thurman and Gerba (1989) suggested that viral inactivation might not require a metabolic process. For instance, the virus may be immobilized to a surface, the host-cell receptors may be blocked, or the nucleic acid within the viral capsid may be inactivated.

Copper is toxic to most microorganisms at higher concentrations, possibly due to the blocking of functional groups on proteins and the inactivation of enzymes (Fernandez et al. 2004). Zinc oxide produces an active oxygen species at its surface that has a similar oxidative effect to hydrogen peroxide when it dissociates. This may damage the viral capsid and allow more metal ions inside the virus.

Unlike the respiratory disease caused by coronavirus 229E, FIPV causes gastrointestinal symptoms. The fact that Ag/Cu zeolite is effective against two substantially different coronaviruses suggests that it may also be effective in reducing the SCoV which causes severe respiratory disease, but which may also have a gastrointestinal component and is shed in the feces for greater than 10 weeks (Leung et al. 2003). The Ag/Cu zeolite was also effective against the nonenveloped feline calicivirus whose physical properties differ greatly from the enveloped coronaviruses.

Zeolite powders containing antiviral heavy metals have many potential applications. They may be added to materials such as plastics, paints, and synthetic fabrics (Quintavalla and Vicini 2002; Takai et al. 2002), and may be bonded to surfaces such as stainless steel (Bright et al. 2002; Cowan et al. 2003; Rusin et al. 2003). The effectiveness of the Ag/Cu zeolite against substantially different viruses appears promising for its potential use in applications to reduce environmental contamination of fomites by viral pathogens and thus the spread of diseases. Additional tests utilizing zeolites containing copper ions alone or in combination with various metals against other disparate viruses are needed.

Acknowledgment The authors would like to thank AgION Technologies for providing the zeolite powders and plastic coupons used in these experiments.

References

Antia, R., Regoes, R. R., Koella, J. C., & Bergstrom, C. T. (2003). The role of evolution in the emergence of infectious diseases. *Nature, 426*, 658–661.

Baker, J., Stevens, D., & Bloomfield, S. F. (2001). Spread and prevention of some common viral infections in community facilities and domestic homes. *Journal of Applied Microbiology, 91*, 7–21.

Bidawid, S., Malik, N., Adegunsin, O., Sattar, S. S., & Farber, J. M. (2003). A feline kidney cell line-based plaque assay for feline calicivirus, a surrogate for Norwalk virus. *Journal of Virological Methods, 107*, 163–167.

Bright, K. R., Gerba, C. P., & Rusin, P. A. (2002). Rapid reduction of *Staphylococcus aureus* population on stainless steel surfaces by zeolite ceramic coatings containing silver and zinc ions. *The Journal of Hospital Infection, 52*, 307–309.

Centers for Disease Control and Prevention. (2003). Revised U.S. surveillance case definition for severe acute respiratory syndrome (SARS) and update on SARS cases—United States and Worldwide, December 2003. *Morbidity and Mortality Weekly Report, 52*, 1202–1206.

Centers for Disease Control and Prevention. (2006). Norovirus: Technical fact sheet. http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-factsheet.pdf. Accessed 22 September 2006.

Chu, C. M., Cheng, V. C. C., Hung, I. F. N., Chan, K. S., Tang, B. S. F., Tsang, T. H. F., et al. (2005). Viral load distribution in SARS outbreak. *Emerging Infectious Diseases, 11*, 1882–1886.

Clay, S., Maherchandani, S., Malik, Y. S., & Goyal, S. M. (2006). Survival on uncommon fomites of feline calicivirus, a surrogate of noroviruses. *American Journal of Infection Control, 34*, 41–43.

Cowan, M. M., Abshire, K. Z., Houk, S. L., & Evans, S. M. (2003). Antimicrobial efficacy of a silver-zeolite matrix coating on stainless steel. *Journal of Industrial Microbiology & Biotechnology, 30*, 102–106.

Davies, R. L., & Etter, S. F. (1997). Development and functions of silver in water-purification and disease-control. *Catalysis Today, 36*, 107–114.

Doultree, J. C., Druce, J. D., Birch, C. J., Bowden, D. S., & Marshall, J. A. (1999). Inactivation of feline calicivirus, a Norwalk virus surrogate. *The Journal of Hospital Infection, 41*, 51–57.

Dowell, S. F., Simmerman, J. M., Erdman, D. D., Wu, J. S. J., Chaovavanich, A., Javadi, M., et al. (2004). Severe acute respiratory syndrome coronavirus on hospital surfaces. *Clinical Infectious Diseases, 39*, 652–657.

Duan, S. M., Zhao, X. S., Wen, R. F., Huang, J. J., Pi, G. H., Zhang, S. X., et al. (2003). Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation. *Biomedical and Environmental Sciences, 16*, 246–255.

Evans, H. S., Madden, P., Douglas, C., Adak, G. K., O'Brien, S. J., Djuretic, T., et al. (1998). General outbreaks of infectious intestinal disease in England and Wales: 1995 and 1996. *Communicable Disease and Public Health, 1*, 165–171.

Fankhauser, R. L., Monroe, S. S., Noel, J. S., Ando, T. A., & Glass, R. I. (2002). Epidemiologic and molecular trends of Norwalk-like viruses associated with outbreaks of gastroenteritis in the United States. *The Journal of Infectious Diseases, 186*, 1–7.

Fernandez, G., Troncoso, M., Navarrete, P., & Figueroa, G. (2004). Antimicrobial activity of copper surfaces against suspensions of *Salmonella enterica* and *Campylobacter jejuni*. *BMC Microbiology, 4*, 19.

Jiang, X., Wang, M., Wang, K., & Estes, M. K. (1993). Sequence and genomic organization of Norwalk virus. *Virology, 195*, 51–61.

Ksiazek, T. G., Erdman, D., Goldsmith, C. S., Zaki, S. R., Peret, T., Emery, S., et al. (2003). A novel coronavirus associated with severe acute respiratory syndrome. *The New England Journal of Medicine, 348*, 1953–1966.

Kwakye-Awuah, B., Williams, C., Kenward, M. A., & Radecka, I. (2008). Antimicrobial action and efficiency of silver-loaded zeolite X. *Journal of Applied Microbiology, 104*, 1516–1524.

Leung, W. K., To, K. F., Chan, P. K., Chan, H. L., Wu, A. K., Lee, N., et al. (2003). Enteric involvement of severe acute respiratory syndrome-associated coronavirus infection. *Gastroenterology, 125*, 1011–1017.

Lopman, B. A., Reacher, M. H., van Duijnhoven, Y., Hanon, F. X., Brown, D., & Koopmans, M. (2003). Viral gastroenteritis outbreaks in Europe, 1995–2000. *Emerging Infectious Diseases, 9*, 90–96.

Mead, P. S., Slutsker, L., Dietz, V., McCaig, L. F., Bresee, J. S., Shapiro, C., et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases, 5*, 607–625.

Myint, S. H. (1994). Human coronaviruses—A brief review. *Reviews in Medical Virology, 4*, 35–46.

Navas-Martin, S., & Weiss, S. (2004). Coronavirus replication and pathogenesis: Implications for the recent outbreak of severe acute respiratory syndrome (SARS), and the challenge for vaccine development. *Journal of Neurovirology, 10*, 75–85.

Payment, P., & Trudel, M. (1993). Isolation and identification of viruses. In P. Payment & M. Trudel (Eds.), *Methods and techniques in virology* (pp. 32–33). New York: Marcel Dekker.

Poutanen, S. M., Low, D. E., Henry, B., Finkelstein, S., Rose, D., Green, K., et al. (2003). Identification of severe acute respiratory syndrome in Canada. *The New England Journal of Medicine, 348*, 1995–2005.

Quintavalla, S., & Vicini, L. (2002). Antimicrobial food packaging in meat industry. *Meat Science, 62*, 373–380.

Rusin, P., Bright, K., & Gerba, C. (2003). Rapid reduction of *Legionella pneumophila* on stainless steel with zeolite coatings containing silver and zinc ions. *Letters in Applied Microbiology, 36*, 69–72.

Shanks, M. J., & Appleton, H. (1998). Feline calicivirus as a model system for heat inactivation studies of small round structured viruses in shellfish. *Epidemiology and Infection, 121*, 401–407.

Smid, B., Vallicek, L., Rodak, L., Stepanek, J., & Jurak, E. (1991). Rabbit haemorrhagic disease: An investigation of some properties of the virus and evaluation of an inactivated vaccine. *Veterinary Microbiology, 26*, 77–85.

Takai, K. T., Okuzaki, T., Senda, Y., Nakao, M., Yamamoto, K., Matsuoka-Inaji, J., et al. (2002). Antibacterial properties of antimicrobial-finished textile products. *Microbiology and Immunology, 46*, 75–81.

Thurman, R. B., & Gerba, C. P. (1989). The molecular mechanisms of copper and silver ion disinfection of bacteria and viruses. *CRC Critical Reviews in Environmental Control, 18*, 295–315.

Tsugeboff, H., & Pratt, D. (1964). The initial steps in infection with coliphage MB. *Virology, 24*, 372–380.

Watanabe, Y., Miyata, H., & Sato, H. (1989). Inactivation of laboratory animal RNA-viruses by physicochemical treatment. *Jikken Dobutsu, 38*, 305–311.

Wilderotter, M. A., Sinka, A., Bulens, S. N., Bond, R. S., Chaves, S. S., Hammond, R., et al. (2005). Norovirus and foodborne disease, United States, 1991–2000. *Emerging Infectious Diseases, 11*, 95–102.

World Health Organization. (2004). *WHO guidelines for the global surveillance of severe acute respiratory syndrome (SARS) Updated recommendations October 2004*. New Delhi, India: Department of Communicable Disease Surveillance and Response, Regional Office for South-East Asia, World Health Organization.

Sciessent

H5N1

Test Report

Redacted

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
& Animal Flu Key-point Open Lab
National Bird Flu Reference Lab of the Ministry of Agriculture

Test Result Certification

2006-1-15

Commissioned by: Beijing SR Science & Technology Co., Ltd. ([redacted])

The product for the test: Inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A)

The title of the test: The in vitro inactivation effect of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against bird influenza virus (H5N1)

Viral strain: H5N1 bird influenza virus

Test method: Refer to the attached Annexes, please.

The in vitro inactivation effect of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against bird influenza virus (H5N1)

Test result:

By adopting Klein-Defors Suspension and having made the 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml of inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) solutions acted on the H5 sub-type bird influenza virus suspension (with the proportion of 9:1) for 10min, the sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the virus in different dilute concentrations is 100%, 99%, 0, 0, 0 .

The sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the H5 sub-type bird influenza virus*

	Inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) (mg/ml)					
	200	100	20	10	4	2
The virus-sterilized & inactivated rate of inorganic antiseptic Zeomic AC10N against virus	100%	99%	0	0	0	0

***The result attests that after 10min action on bird influenza virus, the sterilized and inactivated rate of 200mg/ml inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the virus is 100%, within the range of which the effect to kill virus is conspicuous.**

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
& Animal Flu Key-point Open Lab
National Bird Flu Reference Lab of the Ministry of Agriculture

This Test Report is valid to the supplied sample(s) only.

Test Report

Commissioned by: Beijing SR Science & Technology Co., Ltd.
Tell: 010-82133252
Fax: 010-82133282
Add: Room 1804 of Building No. 10, Sun Garden Resident Quarters, Haidian District, Beijing, China

Tested by: Harbin Veterinary Research Institute of China Agricultural Scientific Academy & Animal Flu Key-point Open Lab & National Bird Flu Reference Lab of the Ministry of Agriculture
Add: No. 427 Maral Street, Nangang District, Harbin City, China
Tell: 0451-85935084

Jan. 2006

Interpretation

1. This Test Report holds true only for the result of the tested contents of the samples delivered for the test.
2. This Test Report would be invalidated if alteration, addition and deletion is found, as well as free from signature and official stamp.
3. Both of this Test Report and the name of this test and verification organization are disallowed to utilize as product label and for advertisement, commercial propaganda and appraisal of high-quality product etc.
4. This Test Report is in quadruplication, two copies are archived by each of the test organization and sample delivery organization respectively.

Add: No. 427 Maxui Street, Nangang District, Harbin, China
Zip code: 150001
Tell: 0451-85935084

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
Animal Flu Key-point Open Lab of the Ministry of Agriculture
National Bird Flu Reference Lab of the Ministry of Agriculture

The in vitro inactivation effect of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against bird influenza virus (H5N1)

This laboratory has conducted the test for the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) delivered by Beijing SR Science & Technology Co., Ltd. for in vitro sterilization and inactivation of influenza virus. The Test Report for the tested result is as follows:

1. Stuff and means for the test

1.1 The product for the test

The inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) is Blue powder, packed with 100g/bag and provided by Beijing SR Science & Technology Co., Ltd. Its lot number is AC0001.

1.2 Viral strain

The viral stain is H5N1 bird influenza virus in sub-type high pathogenicity, which is preserved by relying on Harbin Veterinary Research Institute of China Agricultural Scientific Academy & Animal Flu Key-point Open Lab & National Bird Flu Reference Lab of the Ministry of Agriculture.

1.3 Chick embryo

The Experimental Animal Center of Harbin Veterinary Research Institute of China Agricultural Scientific Academy provided the SPF chick embryo of 10-day's age.

1.4 Test preparation

1.4.1 Determination of virus EID_{50}

Inoculate the H5 sub-type bird influenza that is diluted by 10-time series into the SPF chick embryo of 10-day's age. Each degree of dilution is for 5 chick embryos (0.1ml/embryo), and then to determine the viral half infective dose (EID_{50}).

1.4.2 Preparation for the tested product --the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A)

In the test, first of all dissolve 1g of the inorganic antiseptics of [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) in 5ml sterilized normal saline to be made into 200mg/ml solution for future use.

1.4.3 Toxicity test for the chick embryo of the inorganic antiseptics of [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A)

Inoculate 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml solutions of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) into SPF chick embryo of 10-day's age respectively, and each dilution rate of the solution is for the inoculability of five chick embryos (0.1ml/embryo). Place the inoculated chick embryos in

the 37℃ incubator to cultivate them for 96h. Remove the chick embryo that has died within 24h, and write down the death information of the chick embryos.

1.5 Test for the sterilizing and inactivating rate of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the virus

Klein-Defors suspension method is to be adopted for the test of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) to sterilize and inactivate the high pathogenic bird influenza virus; Made the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) that is diluted with sterilized normal saline acted on the virus for a certain period, and then conduct 10-time series dilution of the mixed dilution in different dilution rates. Then, inoculate the mixed solution into the chick embryos and check the condition of the infected chick embryo.

1.5.1 Suspension sterilizing and inactivating test with Klein-Defors Method

First of all, mix the $10^{7.5}$EID$_{50}$ H5 sub-type bird influenza virus suspension with 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) respectively according to the proportion of 1:9; after 10min process under the temperature condition of 20±1℃, and then have the soak solution diluted with sterilizing normal saline by gradually increasing 10 times to turn out 10 dilution rates; each degree of dilution shall be used for the inoculation of 5 chick embryo (0.1ml/embryo); with regard to the samples in negative control group, sterilized normal saline is substituted for the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) and treated with the same method; inoculate the diluents into the SPF chick embryo of 10-dat age and each dilution rate is for the inoculability of 5 chick embryos (0.1ml/embryo). Place the inoculated chick embryos in the 37℃ incubator for cultivation, and write down the death information of the chick embryo. Remove the chick embryo that died within 24h, take out that died after 24h timely, and take off the entire ones from the incubator till 96h. Take out the allantoic fluid from the dead embryo one by one to perform hemagglutination (HA) test. It should be diagnosed infestation of chick embryo if the hemagglutination (HA) test assumes positive.

Calculate the infectious positive rate, content of EID$_{50}$ in the samples and virus-sterilizing and inactivating rate of the chick embryos in both of the tested group and the control groups according to infectious result of the chick embryo by using the following equation:

The positive rate = the chick embryo quantity that assumes positive in hemagglutinationthe quantity of inoculated chick embryos;

The logarithm for the content of EID50 in the samples = L - d (S - 0.5)

("L" is the logarithm of the minimum dilution multiple, "d" is the logarithmic difference among the degrees of dilution and "S" is the sum of the positive rate of various dilution series).

The sterilized and inactivated rate of the virus = (the content of EID$_{50}$ in the control sample — the content of EID$_{50}$ in the tested sample) / the content of EID$_{50}$ in the control sample x100%.

2. Result

2.1 Determination of virus EID50

It's observed from Table 1 that after the H5 sub-type bird influenza virus is diluted by 10 times in series, having the diluted solution inoculated into the chick embryos of 10-day's age respectively, and each dilution rate of the solution is for 5 chick embryos (0.1ml/embryo), the test result shows that the half infective dose (EID_{50}) of the virus is $10^{7.5}EID_{50}$/0.1ml.

Table 1: Determination of H5 sub-type bird influenza virus EID_{50}

	10-time step-up dilution of H5 sub-type bird influenza virus solution									
	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	10^{-9}	10^{-10}
Infective condition of the chick embryos	5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5	0/5
EID_{50}/0.1ml	$10^{8.5}EID_{50}$/0.1ml									

Note: The numerator is the quantity of the embryo hemagglutination (HA) activity, and the denominator is the quantity of inoculated embryo.

2.2 Toxicity test for the chick embryo applied with the tested product - the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A)

It's observed from Table 1 that after the 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml solution of the inorganic antiseptics [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) is inoculated into SPF chick embryos of 10-day's age respectively, and each dilution rate of the solution is for the inoculability of five chick embryos (0.1ml/embryo), the test result shows that the chick embryo is free from visual pathological change after the application of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) within the dilution rate of the said tests.

Table 2: The maximum non-poisonous dosage of the inorganic antiseptic Zeomic AC10N to chick embryo

	Different dilution rate of the inorganic antiseptic Zeomic AC10N (mg/ml)					
	200	100	20	10	4	2
Death condition of the chick embryos (Piece)	0/5	0/5	0/5	0/5	0/5	0/5

Note: The numerator is the quantity of died embryos, and the denominator is the quantity of inoculated embryos.

2.3 The sterilizing and inactivating effect of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against bird influenza virus

Having made the 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml of

Inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) solutions acted on the H5 sub-type bird influenza virus suspension (with the proportion of 9:1) for 10min, the sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the virus in different dilute concentrations is 100%, 99%, 0, 0, 0 and 0; for the results, refer to Table 3.

Table 3. The sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the H5 sub-type bird influenza virus in different dilute concentrations

Different dilute concentrations of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) (mg/ml)	200	100	20	10	4	2
The virus-sterilized & inactivated rate of inorganic antiseptic Zeomic AC10N against virus	100%	99%	0	0	0	0

3. Conclusion

By adopting Klein-Defors Suspension and Infection Test method to allow the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) to act directly on H5N1 sub-type bird influenza virus (with the proportion of 9:1) in vitro for 10min in different concentrations, so as to detect the sterilizing and inactivating effect of the inorganic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) on bird influenza virus in vitro. The result attests that after 10min action on bird influenza virus, the sterilized and inactivated rate of 200mg/ml inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the virus is 100%, within the range of which the effect to kill virus is conspicuous.

4. References

(1) Lab technical specification in Volume II of the "*Sterilizing Technical Specification*" 2002 - by the Ministry of Public Health

(2) "The Sterilizing & Inactivating Effect of 3-kind of Antiseptics on H5N1 & H9N2 Sub-type Bird Influenza Virus" from the "Collected Papers from the 11th Academic Seminar of the Bird Disease Lodge of the China Animal Husbandry Veterinarian Academy 2002, 10:150 – by Li Yanhua, Tian Guobin, Feng Juyan etc.

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
Animal Flu Key-point Open Lab of the Ministry of Agriculture
National Bird Flu Reference Lab of the Ministry of Agriculture

Jan. 15, 2006

Sciessent

SARS
Test Report

[redacted]-AJ10N
无机抗菌剂体外灭活 SARS 病毒试验总结

试验设计负责人：段淑敏

试验参加者：段淑敏、赵新生、温瑞福、黄晶晶

试验日期：2003 年 9 月~2003 年 10 月

试验单位：中国疾病预防控制中心病毒病预防控制所

试验资料联系电话：010-63536459

委托单位：北京长城永毅科技发展有限公司

中国疾病预防控制中心病毒病预防控制所

2003 年 10 月 7 日

[redacted]-AJ10N 无机抗菌剂体外灭活 SARS 病毒试验总结

摘要：

在非洲绿猴肾传代细胞（VERO E6）培养内，采用病毒(CPE)法，检测[redacted]AJ10N 无机抗菌剂体外对 SARS 病毒的灭活效果，试验结果表明该材料在室温作用 6 小时以上对 SARS 病毒的有一定的灭活作用。

一、 试验目的

检测[redacted]AJ10N 无机抗菌剂在室温情况下与 SARS 病毒作用不同的时间，是否有灭活 SARS 病毒的作用，为加快灭活 SARS 病毒材料的筛选进度提供试验依据。

二、 试验材料

1. 验证材料：

[redacted]-AJ10N 无机抗菌剂：呈白色粉末，每袋 10 克， 由北京长城永毅科技发展有限公司提供

2. 阳性对照药物：

注射用更昔洛韦：批号 020802 由湖北科益药业股份有限公司提供。

3. 病毒：

SARS-COV-P11 冠状病毒分离株（SARS 病人血清 11 号标本）由佑安医院提供，本室分离鉴定。

SARS-COV-P8 冠状病毒分离株 由病毒病预防控制所出血热室（李德新教授提供）。

4. 细胞：

非洲绿猴肾传代细胞（VERO E6），由本室提供。

5. Eagle's 细胞培养维持液等试验材料，均由本室提供。

三、实验方法

1. [redacted]-AJ10N 无机抗菌剂对 VERO E6 细胞的毒性测定

在 VERO E6 细胞培养内，采用细胞形态变化（CPE）法，用 Reed-Muench 法，计算药物半数中毒浓度（TD_{50}）和最大无毒浓度（TD_0）。

[redacted]-AJ10N 无机抗菌剂预处理：

将 6000μg/ml 的 [redacted]-AJ10N 无机抗菌剂放入一容器内，用 Eagle's 细胞维持液稀释后，放在磁力搅拌器上（温度为室温），在搅拌 2 小时、4 小时、6 小时的时候，分别取样进行稀释，即 6000μg/ml~187.5μg/ml，接种 VERO E6 细胞 96 孔培养板。

细胞形态变化 CPE 法：

VERO E6 细胞以 40 万/ml 浓度接种 96 孔培养板，37℃、5%CO_2 培养 24 小时，至细胞单层，分别加入预处理好的 [redacted]-AJ10N 无机抗菌剂，浓度为 6000μg/ml~187.5μg/ml，阳性对照药物倍比稀释为 6000μg/ml~187.5μg/ml，每浓度接种 4 孔，每孔 100μl。同时设正常细胞对照。置 37℃、5% CO_2 培养 5~7 天，每 24 小时在倒置显微镜下观察细胞形态变化，记录细胞形态变化（CPE）：以 25%以下变化为 +，26%~50%变化为 ++，51%~75%为 +++，76%~100%变化为 ++++，试验重复三次。

2. 在 VERO E6 细胞培养内对 SARS-COV-P11 分离鉴定

SARS-COV-P11（SARS 病人 11 号血清分离）：

VERO E6 细胞以每毫升 40 万浓度接种试管，37℃ 5%CO_2 培养 24 小时，弃掉培养液，每管加入 SARS 病人血清 0.2ml，37℃转鼓培养 5 小时后，加入维持液 1ml，同时设正常细胞对照，37℃转鼓培养 5~7 天，细胞出现 CPE 变化后，采用 PCR 的方法检测冠状病毒，11 号标本 PCR 阳性，确定为冠状病毒分离株。用终末稀释法纯化病毒 2 次，PCR 检测，SARS 病毒 S 基因测序仍为阳性，经免疫荧光测定双份 SARS 病人血清，IgM 阳性，IgG4 倍升高，确定为冠状病毒。采用病毒 CPE 法测定其效价。

在 VERO E6 细胞培养内对 SARS-COV-P1 和 SARS-COV-P8 毒株毒力的测定

病毒 CPE 法：

VERO E6 细胞以每毫升 40 万浓度接种 96 孔培养板，37℃ 5%CO_2 培养 24 小时，去掉培养液，分别将 2 株病毒稀释，稀释成 10^{-1} ~ 10^{-8}，8 个浓度，每浓度 4 孔，每孔 100μl，设正常细胞对照，37℃ 5%CO_2 培养 5~7 天，每 24 小时

在倒置显微镜下观察记录细胞形态变化（CPE）：以25%以下变化为“+”，26%~50%变化为“++”，51%~75%为“+++”，76%~100%变化为“++++”，用Reed-Muench法，计算病毒半数感染浓度 $TCID_{50}$。

3. [redacted]-AJ10N 无机抗菌剂在 VERO E6 细胞培养内对 SARS-COV-P11 和 SARS-COV-P8 的灭活作用

试验目的：

在 VERO E6 细胞培养内，采用病毒细胞（CPE）法，观察不同浓度的[redacted]-AJ10N 无机抗菌剂对 SARS 病毒的灭活作用，计算半数有效浓度（IC_{50}）和最小有效浓度（MIC）及治疗指数 TI，判断药效。

100$TCID_{50}$SARS 病毒与[redacted]-AJ10N 无机抗菌剂预处理：

将 2 株 100$TCID_{50}$SARS 病毒稀释液分别与750μg/ml 的[redacted]-AJ10N 无机抗菌剂放在一容器内，在磁力搅拌器上（温度为室温），搅拌 2 小时、4 小时、6 小时分别取样进行稀释，即 750μg/ml~11.7μg/ml，接种 VERO E6 细胞 96 孔培养板。

病毒 CPE 法

VERO E6 细胞以 40 万/ml 浓度接种 96 孔培养板，37℃ 5% CO_2孵箱培养 24 小时，细胞培养至单层，弃掉培养液。加入经 SARS 病毒与[redacted]AJ10N 无机抗菌剂预处理的溶液，选用对细胞的最大无毒浓度（TD_0）2 倍稀释 7 个浓度即为 750μg/ml～11.7μg/ml，同时设预处理的[redacted]AJ10N 无机抗菌剂对照，2 倍稀释 7 个浓度即 750μg/ml～5.9μg/ml，设阳性对照药物注射用更昔洛韦，药物选用对细胞的最大无毒浓度（TD_0）2 倍稀释 7 个浓度即 6000μg/ml～5.9μg/ml，将稀释好的药物分别加入细胞孔内，每浓度 4 孔，同时设正常细胞对照和病毒对照，置 37℃ 5% CO_2培养箱培养 5~7 天，逐日在倒置显微镜下观察病毒 CPE，以病毒对照出现+++ — ++++时结束试验，用 Reed - Muench 法，计算药物的半数有效浓度（IC_{50}）和最小有效浓度（MIC）及治疗指数（TI）判断药效，试验重复三次。

四、试验结果

预备试验结果：

[redacted]AJ10N 无机抗菌剂对 VERO E6 细胞的毒性作用：

由北京长城永科技有限公司提供的[redacted]AJ10N无机抗菌剂和阳性对照药物注射用更昔洛韦在 VERO E6 细胞培养内，采用细胞形态变化（CPE）法。计算该材料的最大无毒浓度（TD_0）和半数中毒浓度（TD_{50}），以下试验结果为三次试验结果的均值。

1. [redacted]AJ10N 无机抗菌剂对 VERO E6 细胞的毒性试验结果

验证材料：

[redacted]AJ10N 无机抗菌剂：最大无毒浓度（TD_0）为 750±0μg/ml，半数中毒浓度（TD_{50}）为 1500±0μg/ml

阳性对照药物：

注射用更昔洛韦：最大无毒浓度（TD_0）为>6000±0μg/ml，半数中毒浓度（TD_{50}）为>6000±0μg/ml 。

2. 在 VERO E6 细胞培养内对 SARS-COV-P11、SARS-COV-P8 毒力测定结果

SARS-COV-P11：半数感染量（$TCID_{50}$）为 10^{-7}

SARS-COV-P8：半数感染量（$TCID_{50}$）为 10^{-7}

正式试验结果

1. [redacted]AJ10N 无机抗菌剂与 SARS-COV-P11 分别作用 2 小时、4 小时、6 小时后，在 VERO E6 细胞培养内检测灭活的效果，分别以 IC50、MIC、TI 和灭活%为指标（以下试验数据为三次试验结果的均值）

检测灭活的效果（以 IC50、MIC、TI 为指标）

验证材料：

[redacted]-AJ10N 无机抗菌剂：

室温作用 2 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 4 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 6 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 94±0μg/ml，最小有效浓度（MIC）为 46.8±0μg/ml ，治疗指数（TI）为 16。

检测灭活的效果（以灭活%为指标）

室温作用 2 小时：病毒 CPE 法，当[redacted]-AJ10N 无机抗菌剂稀释浓度>375μ

g/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 4 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 6 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>188μg/ml 即可灭活 100%的 SARS 病毒，稀释为 94μg/ml 时可灭活 50%的 SARS 病毒，稀释为 46.8μg/ml 时可灭活 25%的 SARS 病毒。

阳性对照药物：

注射用更昔洛韦：CPE 法，药物半数有效浓度（IC_{50}）为 11.7±0μg/ml ，最小有效浓度（MIC）为 23.44±0μg/ml，治疗指数（TI）为 256。

2. [redacted]-AJ10N 无机抗菌剂与 SARS-COV- P8 作用 2 小时、4 小时、6 小时后，在 VERO E6 细胞培养内检测灭活的效果，分别以 IC50、MIC、TI 和灭活%为指标（以下试验数据为三次试验结果的均值）

检测灭活的效果（以 IC50、MIC、TI 为指标）

验证材料：

[redacted]-AJ10N 无机抗菌剂：

室温作用 2 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 4 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 6 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 94±0μg/ml，最小有效浓度（MIC）为 46.8±0μg/ml ，治疗指数（TI）为 16。

检测灭活的效果（以灭活%为指标）

室温作用 2 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 4 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病

毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 6 小时：病毒 CPE 法，当 [redacted]AJ10N 无机抗菌剂稀释浓度>188μg/ml 即可灭活 100%的 SARS 病毒，稀释为 94μg/ml 时可灭活 50%的 SARS 病毒，稀释为 46.8μg/ml 时可灭活 25%的 SARS 病毒。

阳性对照药物：

注射用更昔洛韦：CPE 法，药物半数有效浓度（IC_{50}）为 11.7±0μg/ml，最小有效浓度（MIC）为 23.44±0μg/ml，治疗指数（TI）为 256。

总　　结

由北京长城永毅科技发展有限公司提供的 [redacted]AJ10N 无机抗菌剂和阳性对照药物注射用更昔洛韦在 VERO E6 细胞培养内，采用病毒 CPE 法，在 2 株 SARS 病毒分离株上进行验证，试验结果表明 [redacted]AJ10N 无机抗菌剂和 SARS 病毒在室温作用 6 小时以上，对 SARS 病毒有一定的灭活作用。

试验设计负责人：段源敏

试验参加者：段源敏、赵新生、温瑞福、黄晶晶

试验日期：2003 年 9 月~2003 年 10 月

试验单位：中国疾病预防控制中心病毒病预防控制所

实验病毒资源中心

试验资料联系电话：010-63536459

委托单位：北京长城永毅科技发展有限公司

中国疾病预防控制中心病毒病预防控制所

2003 年 10 月 7 日

Sciessent

Nexera Medical

Mask Utilizing Silver Zeolite Technology

K120244

JUL 5 2012

NEXERA MEDICAL

Section 5.0: 510(k) SUMMARY

510(k) Owner:	NexEra Medical, Inc. 3343 West Commercial Blvd, Suite 103 Ft. Lauderdale, FL 33309	
	Contact:	Paul Sallarulo, President CEO
	Phone:	954-495-2020, x 2031
	Fax:	954-491-7281
Establishment Registration Number:	TBD	
Date Summary Prepared:	July 2, 2012	
Device:	Trade Name:	SpectraShield model 9500 Surgical Mask
	Common /Classification Name:	Surgical mask
	Classification Product Code:	ONT
	Regulation Number:	21CFR 878.4040
Predicate Device Information:	K090414 SpectraShield 9500 Surgical N95 Respirator	
Device Description:	The SpectraShield model 9500 Surgical Mask is a molded shape surgical mask composed of 4 layers of material, molded to form the mask. A 2-ply meltblown polypropylene middle layer is sandwiched by inner and outer layers of 100% polyester nonwoven fabric. The inner and outside layers of polyester nonwoven fabric include fibers that have been embedded with an antibacterial agent to provide antibacterial performance. The mask has 2 latex-free non-allergenic elastic straps and an aluminum nose strip.	
Intended Use:	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, **tested for continuous use up to 8 hours,** embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the	

surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions.

No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.

510(k) Summary
Device Comparison Table

	New Device	Predicate Device
510(k) #	To be determined	K090414
Company	NexEra Medical, Inc.	NexEra Medical, Inc.
Name/Model	**SpectraShield 9500 Surgical N95 Respirator *** (*with amended Intended use Statement)	**SpectraShield 9500 Surgical N95 Respirator**
Fabrics	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.
Nosepiece	100% Aluminum	100% Aluminum
Straps	(2) Polyamide fiber and elastic straps, latex free	(2) Polyamide fiber and elastic straps, latex free
Mask Style	Molded shape	Molded shape
Fluid Resistance ASTM F1862	Pass: Fluid Resistant @ 160mm Hg	Pass: Fluid Resistant @ 160mm Hg

	New Device	Predicate Device
	within safe orally ingestible levels.	within safe orally ingestible levels.
BioEfficacy :	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.40log_{10}reduction - 1 hour *H.influenzae*: > 6.20log_{10}reduction - 1 hour MRSA: > 4.83log_{10}reduction - 1 hour	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.40log_{10}reduction - 1 hour *H.influenzae*: > 6.20log_{10}reduction - 1 hour MRSA: > 4.83log_{10}reduction - 1 hour
BioEfficacy : after repeated exposures to perspiration over 12 hours	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.25log_{10}reduction - 1 hour *H.influenzae*: > 4.18log_{10}reduction - 1 hour MRSA: > 4.11log_{10}reduction - 1 hour	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.25log_{10}reduction - 1 hour *H.influenzae*: > 4.18log_{10}reduction - 1 hour MRSA: > 4.11log_{10}reduction - 1 hour
Intended Use Statement	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, **tested for continuous use up to 8 hours**, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator. The SpectraShield 9500 Surgical N95

	New Device	Predicate Device
	The SpectraShield 9500 Surgical N95 respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.	respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.

Conclusion: The subject device (SpectraShield model 9500 Surgical mask with the revised IFU referencing "tested for continuous use up to 8 hours"), and the predicate device (K090414) are the same device. The intention of this 510k submittal is to change the IFU to include the statement **"tested for continuous use up to 8 hours".**

The predicate device (K090414) was tested for bio-efficacy after repeated exposures to perspiration over a 12 hour period (see K090414 Repeat Challenge Protocol and Testing). The repeat challenge testing required the predicate device be repeatedly exposed to perspiration over a 12 hour period. Following the 12 hour exposure the predicate device was tested and demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. The intention of the repeated challenge and sustained exposure was to demonstrate that the device would still function as intended (99.99% kill) after wearing the device for 12 hours.

The IFU for the predicate device references "single use, disposable device". The proposed change to the IFU would read "single use, disposable device, tested for continuous use up to 8 hours."

It is our conclusion that the proposed change to the IFU does not change the intended use of the device, and we believe the change to the IFU further clarifies the intended use of the device. Additionally, we note the proposed change to the IFU demonstrate the device is as safe and as effective as the predicate device and performs equally as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G6
Silver Spring, MD 20993-0002

JUL 5 2012

Mr. Paul Sallarulo
Nexera Medical Incorporated
3343 West Commercial Boulevard Suite 103
Fort Lauderdale, Florida 33309

Re: K120244
Trade/Device Name: SpectraShield Model 9500 Surgical Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: ONT
Dated: June 21, 2012
Received: June 25, 2012

Dear Mr. Sallarulo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0: Indications for Use Statement

510(k) Number: 510(k) submission K12 0244

Device Name: SpectraShield model 9500 Surgical Respirator

Indications for Use:

The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable, surgical N95 respirator, tested for continuous use up to 8 hours, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: Streptococcus pyogenes, MRSA (Methicillin Resistant Staphylococcus aureus), and Haemophilus influenzae, under tested contact conditions.

No clinical studies have been conducted comparing the ability of an untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection, and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device, intended for occupational use to protect against microorganisms, body fluids, and particulate material.

Prescription Use _____ AND/OR Over –the-counter Use _X_
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120244

Sciessent

Sciessent

Sciessent

Agion AM-B10G

Michael D. Abbott
Michael.Abbott@Hanes.com

03/21/2020

Outline

Agion Chemistry Summary

- Company
  - Sciessent
    - www.sciessent.com
- Chemical Name
  - Agion AM-B10G
  - Application rate
    - 1.50% OWG(on weight of goods)
    - Grams/Sq Meter will be supplied by Sciessent
- TDS/SDS is attached
- Application method will be provided by Sciessent based on available equipment
  - Exhaust
  - Pad
  - Foam
  - Etc.
- Sales Contact
  - Meg McComb
  - mmccomb@sciessent.com
  - Mobile: (339) 293-9097
- Technical Support
  - Frank Stevens
  - fstevens@sciessent.com
  - Mobile: +1 (562) 343-4199

AGION AM-B10G

SDS

SCIESSENT LLC

Safety Data Sheet
Agion® AM-B10G Slurry

SECTION 1: Identification

Product identifier

Product name	Agion® AM-B10G Slurry
Brand	Agion®

Other means of identification
Antimicrobial treatment for textiles

Supplier's details

Name	Sciessent LLC
Address	100 Cummings Center Suite 251-G Beverly, MA 01915 USA
Telephone	781-224-7100
email	EHS coordinator - info@sciessent.com

Emergency phone number(s)

Chem TREC (24 hour) 1-800-424-9300 or +1-703-527-3887

SECTION 2: Hazard identification

General hazard statement
Hazardous to the aquatic environment, short term, acute. Category 1.
Hazardous to the aquatic environment, long-term, chronic. Category 2.

Classification of the substance or mixture

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

GHS label elements, including precautionary statements

Pictogram

Hazard statement(s)

H400	Very toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects

Precautionary statement(s)

P273	Avoid release to the environment.
P391	Collect spillage.
P501	Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

SECTION 3: Composition/information on ingredients

Mixtures

Hazardous components

1. Silver copper zeolite

Concentration	10 - 15 % (weight)
CAS no.	130328-19-7

2. Silver zeolite

Concentration	5 - 10 % (weight)
CAS no.	130328-18-6

3. Water

Concentration	50 - 60 % (weight)
EC no.	231-791-2
CAS no.	7732-18-5

4. Acrylic polymer resins

Concentration	20 - 30 % (weight)
CAS no.	38054-57-8

5. Propylene glycol

Concentration	1 - 3 % (weight)
EC no.	200-338-0
CAS no.	57-55-6

6. Polyurethane resin

Concentration	1 - 2 % (weight)
CAS no.	67700-43-0

SECTION 4: First-aid measures

Description of necessary first-aid measures

If inhaled	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

In case of skin contact	Immediately wash skin with soap and plenty of water. Get medical attention if irritation develops or persists.
In case of eye contact	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Remove contacts if present and easy to do. Continue rinsing. Get medical attention, if irritation or symptoms of overexposure persists.
If swallowed	If swallowed, do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

Personal protective equipment for first-aid responders
As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Most important symptoms/effects, acute and delayed
Refer to Section 2 and/or Section 11.

Indication of immediate medical attention and special treatment needed, if necessary
None.

SECTION 5: Fire-fighting measures

Suitable extinguishing media
Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.

Specific hazards arising from the chemical
None

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures
Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Use proper personal protective equipment as listed in Section 8.

Environmental precautions
Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up
SMALL SPILLS: Contain and absorb with absorbent material and place into containers for later disposal. Wash site of spillage thoroughly with water. LARGE SPILLS: Dike far ahead of spill to prevent further movement. Recover by pumping or by using a suitable absorbent material and place into containers for later disposal. Dispose in suitable waste container.

Reference to other sections
For disposal see section 13.

SECTION 7: Handling and storage

Precautions for safe handling
Use with adequate ventilation. Avoid breathing vapor and contact with eyes, skin and clothing.

Conditions for safe storage, including any incompatibilities
Store in a cool, dry, well ventilated area away from sources of heat, combustible materials, and incompatible substances. Keep container tightly closed when not in use.
Do not store below 40° F (4° C) to protect from freezing or above 120°F (50° C) to maintain product quality. Store in a tightly closed corrosion resistant container to prevent evaporation of water and the introduction of contaminants that can adversely affect performance.

Specific end use(s)
Slurry should be thoroughly mixed prior to use to ensure uniform dispersion, since settling will occur during prolonged storage. Particular attention should be paid to the bottom of the container to ensure homogeneous composition.

SECTION 8: Exposure controls/personal protection

Control parameters

1. Propylene glycol (CAS: 57-55-6 EC: 200-338-0)
TWA (inhalation): 10 mg/m3; USA (OSHA)
USA. Workplace Environmental Exposure Levels (WEEL)

Appropriate engineering controls
Use appropriate engineering controls such as process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Good general ventilation should be sufficient to control airborne levels. Where such systems are not effective wear suitable personal protective equipment, which performs satisfactorily and meets OSHA or other recognized standards. Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

Individual protection measures, such as personal protective equipment (PPE)

Pictograms

Eye/face protection
Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Chemical-resistant gloves and chemical goggles, face-shield and synthetic apron or coveralls should be used to prevent contact with eyes, skin or clothing.

Body protection
Chemical-resistant gloves and chemical goggles, face-shield and synthetic apron or coveralls should be used to prevent contact with eyes, skin or clothing.

Respiratory protection
Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance/form (physical state, color, etc.)	Blue Slurry
Odor	Not determined.
Odor threshold	Not determined.
pH	7 - 9
Melting point/freezing point	Not determined.
Initial boiling point and boiling range	> 100 C
Flash point	> 100 C
Evaporation rate	Not determined.
Flammability (solid, gas)	Not applicable
Upper/lower flammability limits	Not applicable
Vapor pressure	Not determined.
Vapor density	Not determined.
Relative density	~9 lbs/gal (1.07 g/cm3) @25°C
Solubility(ies)	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not applicable
Decomposition temperature	Not determined.
Viscosity	Not applicable
Explosive properties	Not determined.
Oxidizing properties	Not determined.

SECTION 10: Stability and reactivity

Reactivity
No data available

Chemical stability
Stable under recommended storage conditions.

Possibility of hazardous reactions
None under normal use conditions.

Conditions to avoid
Heat, flames, and incompatible materials. Temperature below 40° F (4° C) or above 120°F (50° C).

Incompatible materials

—

Propylene glycol: Acid chlorides, Acid anhydrides, Oxidizing agents, Chloroformates, Reducing agents

Hazardous decomposition products

—

Water: In the event of fire: see section 5

—

Propylene glycol: Other decomposition products - No data available
In the event of fire: see section 5

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity
Silver Copper Zeolite:
Inhalation: Inhalation Rat LC50: > 2.59 m g/L/4hr (Manufacturer Studies)
Ingestion: Ingestion Rat LD50: > 5 gm/kg (Manufacturer Studies)

Silver Zeolite :
Dermal Rat LD50: > 2 gm/kg
Ingestion Rat LD50: > 5 gm/kg (Manufacturer Studies)
Inhalation Rat LC 50: > 18,300 mg/m 3/1hr (TS: zeolite s A) (OECD SIDS)

Skin corrosion/irritation
Silver Copper Zeolite:
Skin Rat: Slight Irritation. (Manufacturer Studies)

Silver Zeolite:
Skin Rat: No significant irritation (Manufacturer Studies)

Respiratory or skin sensitization
Silver Copper Zeolite:
Skin Guinea pig: Not sensitizing. (Manufacturer Studies)

Silver Zeolite:
Skin Rat: No significant irritation (Manufacturer Studies)

Germ cell mutagenicity
Silver Copper Zeolite:
In vitro Ames test: Non mutagenic. (Manufacturer Studies)

Silver Zeolite
Invitro Ames test: Non mutagenic.
In vivo Chromosome Aberration Assay: Silver Zinc Zeolite did not cause an increase in chromosomal aberrations at any time point in either male or female rats. (Manufacturer Studies)

Carcinogenicity
Not listed in IARC, NTP, or OSHA.

STOT-single exposure
No data available on product

STOT-repeated exposure
No data available on product

Aspiration hazard
No data available on product

SECTION 12: Ecological information

Toxicity
Ecotoxicity: No data available for this product.

Persistence and degradability
No data available on product

Bioaccumulative potential
No data available on product

Mobility in soil
No data available on product.

Other adverse effects
Silver Copper Zeolite:
Effect of Material On Aquatic Life:
Pimephales promelas LC50 96 h 1.2 µg/L (Silver)
Daphnia magna LC50 48 h 0.22 µg/L (Silver)
Danio rerio NOEC 35 d 5.9 µg/L (Silver)
Ceriodaphnia dubia EC10 7 d 2.48 µg/L (Silver)
Nostoc muscorum EC 10 15 d 0.16 µg/L (Silver)(ECHA)

Silver Zeolite:
Effect of Material On Aquatic Life: Oncorhynchus kisutch 96 h LC 50 820 µg/L (TS: Zinc chloride)
Daphnia magna 48 h LC 50 330 µg/L (TS: Zinc chloride)
Pseudokirchnerella subcapitata 72 h NO EC 5.4 µg/L (TS: Zinc chloride)
Oncorhynchus mykiss 30 d NO EC 39 µg/L (TS: Zinc chloride) (ECHA)

SECTION 13: Disposal considerations

Disposal of the product
Dispose of contents/ container in accordance with the local/regional/national/international regulations.

SECTION 14: Transport information

DOT (US)
UN Number: Not regulated as hazardous material for transportation.
Proper Shipping Name: Not regulated as hazardous material for transportation.

IMDG
UN Number: UN3082
Class: 9
Packing Group: III
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (silver zeolite, silver copper zeolite)

IATA
UN Number: UN3082
Class: 9
Packing Group: III
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (silver zeolite, silver copper zeolite)

SECTION 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

SARA 313 Components
SARA 313 Listed, N740 Silver Compounds (8%), N100 Copper Compounds (12%)

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

New Jersey Right To Know Components
Propylene glycol
CAS number: 57-55-6

Pennsylvania Right To Know Components
Propylene glycol
CAS number: 57-55-6

SARA 302 Components
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

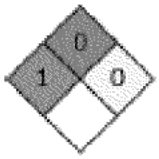
SARA 311/312 Hazards
No SARA Hazards

Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

HMIS Rating

Agion® AM-B10G Slurry	
HEALTH	1
FLAMMABILITY	0
PHYSICAL HAZARD	0
PERSONAL PROTECTION	X

NFPA Rating



SECTION 16: Other information

SDS Revision Date: January 01, 2020
SDS Revision Notes: Revision 6

Further Information/disclaimer
This SDS is valid for all countries in North America, South America, China, Taiwan, India, Japan, Bangladesh, Pakistan, Malaysia and Sri Lanka

AGION AM-B10G

TDS

TECHNICAL DATA SHEET

Agion® AM-B10G Slurry

Description: Agion® AM-B10G Slurry is a textile finishing agent that provides excellent antimicrobial performance to a wide variety of fabrics. It is a bluish tinted, aqueous based dispersion with type A zeolite powder containing ionic silver and copper. Agion® AM-B10G Slurry has an acrylic resin base so that no additional components are required. This formulation has been designed for use on fabric, garment and other similar applications. Agion AM-B10G is free of Zinc.

Product Specification: The material is tested according to the test procedure included in the *"Inspection Standard"*, and must comply with the following specification values:

Parameter	Analytical Method	Unit	Specification Value
Copper Content	Atomic Absorption	Wt%	0.63-0.89
Silver Content	Atomic Absorption	Wt%	0.65-0.93
Particle Size Distribution	Laser Particle Analysis	µm	Mean less than 5
Percent Solids	Gravimetric Analysis	Wt%	35-50%

Typical Properties*:

Appearance	Bluish tint dispersion
Crystal Structure of Solids	Type A Zeolite
pH in water	6-9
(Weight per gallon, lb. @25°C	~9

****These items are provided as general information only. They are approximate values and are not considered part of the product specification.***

Storage and Handling:

Agion® AM-B10G Slurry should be stored in a tightly closed corrosion resistant containers to prevent evaporation of water and the introduction of contaminants that can adversely affect performance.

Do not store below 40° F (4°C) to protect from freezing or above 104°F (40°C) to maintain product quality.

Agions AM-B10G Slurry should be thoroughly mixed prior to use to ensure a uniform dispersion, since settling will occur during prolonged storage. Particular attention should be paid to the bottom of the container to ensure homogeneous composition. In the case of large storage containers like totes, it is recommended to mix the tote with a suitable motor driven mixer, electric or air powered, at least once per day for approximately 30 minutes prior to use.

Do not use galvanized fittings or connections with AM-B10G. Only use stainless steel or PVC.

Further dilution of slurry with a suitable solvent may reduce the stability of the dispersion and continuous agitation during processing may be required to ensure uniform distribution.

Because Sciessent LLC does not control the use, processing or method of use to which others may put its antimicrobial agents, Sciessent does not guarantee the effectiveness or suitability of the agents for use in any particular process, application or article of manufacture. These agents are not suitable for or efficacious in all applications to which a user may desire to apply them. The user of any agent described in this Technical data Sheet should conduct their own tests to determine the suitability of the agent in their particular process, application or article of manufacture.

Sciessent LLC warrants that its products in the original, sealed containers will meet the product specifications for a period of three (3) months from the date of Shipment.

SCIESSENT DISLCAIMS ALL WARRANTIES, WHETHER EXPRESSED, IMPLIED, OR STATUTORY, INCLUDING THE WARRANTIES OF MECHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT SHALL SCIESSENT BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES HOWSOEVER ARISING. BUYER'S SOLE AND EXCLUSIVE REMEDY AGAINST SCIESSENT FOR ANY CAUSE OF ACTION ARISING OUT OF THE SALE OR USE OF ANY PRODUCT HEREIN DESCRIBED SHALL BE REPLACEMENT OF THE PRODUCT OR REFUND OF THE PURCHASE PRICE PAID FOR THE PRODUCT.

Sciessent

Silver Copper Type AC Label 3.27.15

Agion® Silver Copper Type AC

A preservative and bacteriostatic agent for use in the manufacture of polymer, plastic, latex products.
For commercial and industrial use only.

Active Ingredient:	
Silver	3.52 %
Copper	6.1 %
Other Ingredients	90.38 %
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Manufactured for:
Sciessent LLC
60 Audubon Rd
Wakefield, MA 01880

EPA Registration No. 71227-7-88165
EPA Establishment No. 88165-MA-001

Net Wt. XXXX

Lot No. XXXXXXXXX

NSF

Standard 51 Listed

Nonfood Compounds
Program Listed PX

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For all uses listed*:

* Do not incorporate this product into any food contact polymer unless the subject food contact polymer is approved and listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System." Any incorporation of this product into an approved and listed food contact polymer must comply with the specific use conditions listed in 21 CFR, Parts 174 through 186 (inclusive), or in the United States Food and Drug Administration's "Food Contact Substance Notification System," for such food contact polymer. Any incorporation of this product into any food contact substance (including but not limited to non-polymer substances) other than an approved and listed food contact polymer is prohibited.

* For applications involving direct or indirect food or human drinking water contact, Agion® Silver Copper Antimicrobial Type AC must be used with an FDA approved polymer or coating. Non-food and non-drinking water contact applications can use either FDA or non-FDA approved coatings.

* This product may be used for the following human drinking water contact uses:
  - water filter components and housing units
  - water bottle dispensers and components
  - water dispensers
  - ice machine trays
  - ice machine bins
  - ice machine water hoses
  - ice dispensers and other ice machine components
  - water bottles
  - cups
  - water storage vessels

* This product may be incorporated into food and water bowls, dishes and other containers used by domestic animals. Do not use for any food or drinking water applications involving non-domestic animals.

Agion® Silver Copper Antimicrobial Type AC. is an antimicrobial additive to be used by compounding into many polymeric materials. It is designed to be incorporated during the manufacturing process to impart antimicrobial activity to the manufactured products. *Agion® Silver Copper Antimicrobial Type AC* suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining, deterioration or corrosion only. No finished product incorporating *Agion® Silver Copper Antimicrobial Type AC* may make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the finished product which permits such claims. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

Types of Finished Products

Plastics - including films, sheets, slabs, and molded plastic parts

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.3% for bulk plastics. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer):

Packaging
Gaskets
general purpose containers
food and drink containers
food trays and covers
sponges
tubing
brush bristles (including personal care grooming items, toothbrushes), and cosmetic brushes
liners
non-woven fabrics,
plastic sheeting for construction and agricultural applications
appliances and equipment
kitchen and food processing utensils and Supplies
cutting boards
countertops
sinks
tiles
dishes, cups, bottles
conveyor belts
food processing equipment (including slicers formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders choppers, peelers and countertops)
beverage processing equipment (including mixers, transfer equipment, pumps, bottlers canners, dispensers and fermenters)
building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

Non-food contact uses only:

Automobile Parts
Mats
Waste containers
Mops
Plumbing supplies and fixtures
Siding for housing
Flooring
Insulation for wire and cable
Indoor and outdoor furniture
Spas, bathtubs, showers, filters and components thereof
Office equipment and supplies (including binders, filing and storage systems, pens, pencils, markers, printers, facsimile machines, desk accessories, computers, keyboards, mice scanners, and printers).
Medical devices, equipment and supplies
Shower curtains
Protective Covers
Brush handles
Vacuum cleaner bags
Drain pan liners
Kitchen and bathroom hardware
Floor coverings
Insulators
Plastic building materials
Garbage bags and garbage cans
Telephones, mobile devices, head phones, head sets and accessories
Cameras and imaging equipment

Fibers – including cotton, rayon and synthetically derived fibers

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.5% for fibers. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating on an article):
Synthetic and Natural Fibers
napkins, tablecloths and wiping cloths
bags
brush bristles (including personal care grooming items, toothbrushes and cosmetic brushes)
filters
clothing apparel (including uniforms, outerwear, gloves, aprons, coats and shoes)
sponges
packaging (including bags, sacks, wraps, cushion and absorbent materials, and containers)
conveyor belts
kitchen, commercial and industrial wipes and fabrics

Non-food contact uses only:
Synthetic and Natural Fibers
Paper for gypsum board.
Paper, paperboard, composite building materials

Interior furnishings -
mattress cover pads and filling
pillow covers
sheets
blankets
fiberfill for quilts and pillows
curtains
draperies
carpet and carpet underlay
rugs
upholstery
mops
towels
wall covering fabrics
cushion pads
sleeping bags

Apparel –
umbrellas
outerwear
sportswear
sleepwear
stockings
socks and hosiery
caps
undergarments
inner liners for jackets
trim for outerwear and garments
medical devices, equipment and supplies

Transportation –
automotive and truck upholstery
carpeting
rear decks
trunk liners
convertible tops
interior liners

Industrial and Other Household Items -
artificial leather
filters
book covers
mops
cloth for sails
ropes
tents and other outdoor equipment
tarps
awnings
drain pan liners

Luggage -
Sports bags
Shoe bags
Sports bag accessories
Luggage
Duffel bags
Laundry bags
Cosmetic bags
Packing Organizers
Luggage Lining

Coatings, Films and Laminates

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for coatings. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder emulsion, starch, cellulosic, lacquer, thermoset, thermoplastic, thermal spray coatings including pre-dispersions and components thereof.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer, or as a FDA-approved polymer coating, film or laminate on an article):
packaging
paper products (including wipes and tissues)
natural and synthetic fibers and fabrics
sinks
countertops
cutting boards
dishes
cookware
general purpose containers
kitchen, commercial and industrial utensils and supplies
collection and storage equipment (including conveyor belts, piping systems, silos, tanks and process vessels)
appliances and food processing equipment (including slicers, formers, juicers, washers, canners, freezers, refrigerators, shelving, cookers, grinders, choppers, peelers and countertops)
beverage processing equipment (including mixers, transfer equipment, pumps, bottlers, canners and fermenters and dispensers)
building materials and components (including walls, hardware, floors, ceilings and components thereof for kitchen, commercial and industrial applications)

Non-food contact uses only:

Building Materials (including gypsum board, insulation, cellulose or fiberglass ceiling tile, and polymer flooring.)
Heating, Ventilation and Air Conditioning equipment and related materials (including insulation, ducts, heat exchangers, drain pans, air filters, air purifiers, diffusers, and parts and components thereof)[1]
Industrial equipment
Furniture
Automotive and vehicular parts
Packaging
Siding
Roofing
Shingles
Industrial equipment
Medical devices, equipment and supplies

Luggage -
Sports bags
Shoe bags
Sports bag accessories
Luggage
Duffel bags
Laundry bags
Cosmetic bags
Packing Organizers
Luggage Lining

Adhesives and Sealants

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.5% for adhesives and sealants. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer incorporated into FDA-approved adhesives or sealants):
plumbing adhesives
pipe sealants and insulating materials
grout and joint compound for; countertops, building materials and components, and food and beverage related equipment

Non-food contact uses only:
Adhesives, joint compound and grout for gypsum board, ceramic tile, wood, paper, cardboard, rubber and plastic.
Medical devices, equipment and supplies

Miscellaneous Applications

The additive may be incorporated into the finished product at up to 5.0% by weight. Contact Sciessent LLC to determine the appropriate amount of Agion® Silver Copper Antimicrobial Type AC for individual finished products.

Food contact* and non-food contact uses (in all food contact cases, when the article itself is a FDA-approved polymer or coating.

Interior paints and coatings
Stucco
Plaster
Leather
Medical devices, equipment and supplies

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: Caution. Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling and before eating, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water of 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If inhaled	• Move person to fresh air. • If person if not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If swallowed	• Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

Storage and Disposal

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Do not store in areas accessible to children. Keep product dry and containers covered during storage; store below 130°F.

Container Disposal: Nonrefillable container. Do not reuse or refill inner plastic bag or outer steel can. **Inner Plastic Bag:** Completely empty plastic bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. **Outer Steel Can:** Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Pesticide Disposal: Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.

Gerba

Anti-Viral Properties of Agion

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ORIGINAL PAPER

Assessment of the Antiviral Properties of Zeolites Containing Metal Ions

Kelly R. Bright · Enue E. Sicairos-Ruelas · Patricia M. Gundy · Charles P. Gerba

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Abstract The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-$\log_{10}$ reduction within 24 h. It was also the most effective (>3.18-$\log_{10}$) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-$\log_{10}$ and >3.8-$\log_{10}$ reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.

Keywords Coronavirus · Calicivirus · Fomites · Antiviral · Copper · Silver

Introduction

By July of 2003, 8,098 probable cases of severe acute respiratory syndrome (SARS) resulting in 774 deaths had been reported to the World Health Organization (WHO) from 29 countries on five continents (Centers for Disease Control and Prevention 2003; World Health Organization 2004). A novel coronavirus, SARS coronavirus (SCoV) was isolated from patients (Ksiazek et al. 2003; Navas-Martin and Weiss 2004). Before the identification of SCoV, two coronaviruses were known to infect humans, strains 229E and OC43 (Navas-Martin and Weiss 2004). These cause mild, self-limiting, upper respiratory tract infections (Myint 1994) and belong to the Group I and Group II coronaviruses, respectively. SCoV possesses characteristics specific to all three coronavirus groups (Navas-Martin and Weiss 2004), but is not closely related to any (Poutanen et al. 2003). It is apparently an animal virus that recently adapted to cross the species barrier, allowing for human-to-human transmission (Anzia et al. 2003).

Human norovirus (NoV) causes illness in an estimated 23 million people in the United States each year, resulting in 50,000 hospitalizations and 310 deaths (Mead et al. 1999). It has been suggested that NoV may be the leading cause of foodborne illness in the United States (Widdowson et al. 2005), responsible for approximately 66% of all cases with known etiologies (Mead et al. 1999) and at least 50% of all foodborne outbreaks of gastroenteritis (Centers for Disease Control and Prevention 2006). NoV was identified in 93% of nonbacterial gastroenteritis outbreaks by the Centers for Disease Control and Prevention (CDC) between 1997 and 2000 in the United States (Fankhauser et al. 2002). Similarly, surveillance by the Foodborne Viruses in Europe network found that NoV was responsible for greater than 85% of all nonbacterial gastroenteritis outbreaks from 1995 to 2000 (Lopman et al. 2003).

Nonenveloped viruses are typically more resistant to environmental conditions and the action of antimicrobials

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than enveloped viruses (Watanabe et al. 1989; Barker et al. 2001). Feline calicivirus has been found to persist for up to 28 days in a dry environment at room temperature (Doultree et al. 1999). Also, in a study by Smid et al. (1991), rabbit hemorrhagic disease virus (also a calicivirus) survived for at least 105 days in a dried state at room temperature. Viruses that cause symptoms such as vomiting or diarrhea are likely to contaminate the environment. In one study, 607 of 680 (89%) norovirus outbreaks were linked to person-to-person transmission (Evans et al. 1998) that included poor hand hygiene as well as surface-to-surface transmission (Barker et al. 2001). Also, successive outbreaks of norovirus infections in passengers on cruise ships on separate trips have strongly implicated environmental contamination (Barker et al. 2001). Enveloped viruses are typically less stable in the environment, yet the SCoV is able to survive on fomites for up to 96 h (Duan et al. 2003). The transmission of SCoV is believed to be multifactorial, with evidence from previous outbreaks suggestive of at least some role for contaminated fomites in the transmission of the virus (Dowell et al. 2004; Chu et al. 2005).

Zeolite (sodium aluminosilicate) powders (AgION Technologies, Wakefield, MA, USA) form porous crystals. Metal ions may reside within these pores and zeolites can act as ion exchangers, exchanging metal ions for other cations in the environment. Although the effect of metal-zeolites has been documented in numerous studies with bacteria (Bright et al. 2002; Takai et al. 2002; Cowan et al. 2003; Rusin et al. 2003; Kwakye-Awuah et al. 2008), the use of zeolite powders containing heavy metal ions to reduce coronaviruses and caliciviruses has not been previously reported. This paper describes the antiviral effect of suspensions of zeolite powders amended with silver (Ag), copper (Cu), and zinc (Zn) ions in phosphate-buffered saline against human coronavirus 229E and feline infectious peritonitis virus (FIPV; feline coronavirus). This report also includes tests of the survival of human coronavirus 229E, FIPV, and feline calicivirus on the surfaces of plastics with zeolite containing Ag and Cu ions incorporated into the plastic.

Human coronavirus 229E and FIPV were employed in this study as surrogates for other coronaviruses. Feline calicivirus was also included as a surrogate for NoV. There is currently no practical method for propagating human NoV in cell culture monolayers. Feline calicivirus, on the other hand, grows readily in cell culture. It is in the same family as human NoV and is commonly used as a NoV surrogate in experiments (Slomka and Appleton 1998; Clay et al. 2006) because of its biochemical and genetic similarities to NoV (Jiang et al. 1993).

Materials and Methods

Virus Preparation

Human coronavirus strain 229E (ATCC #VR-740) was obtained from the American Type Culture Collection (ATCC, Manassas, VA, USA). It was maintained on MRC-5 (fetal human lung fibroblast, ATCC #CCL-171) cell line monolayers with minimal essential medium (MEM, modified with Earle's salts, Irvine Scientific, Santa Ana, CA, USA) containing 2% fetal bovine serum (FBS, Hyclone, Logan, UT, USA) at an incubation temperature of 35°C with 5% CO_2. Coronavirus 229E replicates better at this temperature than at 37°C. Feline infectious peritonitis virus (FIPV; ATCC #VR-990) and feline calicivirus strain F-9 (ATCC #VR-782) were maintained in the same manner on CRFK (Crandell Reese feline kidney, ATCC #CCL-94) cell line monolayers.

Viruses were purified by centrifugation (750×*g*) to remove cell debris followed by polyethylene glycol (9% PEG, 0.5 mol/l NaCl) precipitation. Viral titrations were performed using the Reed-Muench method (Payment and Trudel 1993) to determine the tissue culture infectious dose that affected 50% of the cultures ($TCID_{50}$).

Metal-Zeolite Powders in Suspension

Coronavirus strains 229E and FIPV were added to Erlenmeyer flasks containing 30.0 ml of phosphate buffered saline (PBS, pH 7.4; Sigma-Aldrich, St. Louis, MO, USA) with 10.0 mg of suspended zeolite test powder [either unamended powder, 20.0% Ag (w/w), 3.5% Ag/6.5% Cu, or 0.6% Ag/14% Zn/80% ZnO] (AgION Technologies, Wakefield, MA, USA). Positive control flasks without zeolite powder were also included. All experiments were performed in duplicate.

The positive control flasks (without zeolite powders) were sampled immediately ($t = 0$ h) by removing 1.0 ml from each flask and placing it into 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA). The 2.0 ml volumes were mixed thoroughly and placed into 4.0 ml of PBS (pH 7.4). All test flasks were then placed on an orbital shaker (200 rpm) at room temperature (23°C) and were sampled at 1, 4, and 24 h in the manner described previously. All samples were frozen in 1.0 ml aliquots at −80°C. Frozen aliquots were subsequently assayed using the Reed-Muench $TCID_{50}$ method as before (Payment and Trudel 1993).

Plastics with Incorporated Metal-Zeolites

Plastic coupons (5 cm by 5 cm) with either 5 or 10% (w/w) zeolite (containing 3.5% Ag and 6.5% Cu ions) incorporated

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (w/w), but with differing amounts [5 or 10% w/w] of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23°C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

Statistical Analysis

A Student's *t* test was used to compare the viral counts recovered from the flasks containing test powder suspensions and test plastic coupons to those recovered from the positive controls.

Results

Metal-Zeolite Powders in Suspension

Amended zeolite powder suspensions were compared to determine which heavy metal combinations demonstrated the greatest activity against human coronavirus 229E. Unamended powder was used as a control to evaluate the effect of adsorption. The effect of Cu alone was undetermined. The results of the suspension tests are presented in Table 1. The results from the flasks containing zeolite control powder indicate that removal of virus was not due to adsorption by zeolite particles. Of the powder suspensions tested, the 3.5% Ag/6.5% Cu ion combination was the most efficacious, yielding a 1.08-log_{10} reduction of 229E after 1 h, a 2.06-log_{10} reduction after 4 h, and a >5.13-log_{10} reduction after 24 h of exposure. The greatest reductions observed for the other amended powders were following 24 h of exposure; nevertheless, the reductions at 24 h were not significantly greater ($P = 0.274$) than those after 4 h of exposure.

The 3.5% Ag/6.5% Cu combination was also effective (>3.18-log_{10} reduction) against FIPV within 4 h; however, neither of the other formulations was effective against FIPV, even after 24 h of exposure.

Plastics with Incorporated Metal-Zeolites

The results for the virus survival on the plastics with incorporated Ag/Cu-zeolite are shown in Table 2. Significant reductions were observed for coronavirus 229E on the Ag/Cu-zeolite plastic coupons after 24 h of exposure with a 1.84-log_{10} and a 1.77-log_{10} reduction achieved on the 5% and 10% (wt/wt) zeolite coupons, respectively. The

Table 1 Log_{10} reduction of coronaviruses after exposure to zeolite test powders amended with heavy metals

Virus	Time (h)	Positive control[a]	Zeolite control[b]	Amended zeolite powder (w/w)			
				3.5% Ag 6.5% Cu	20% Ag	0.6% Ag 14% Zn 80% ZnO	
229E (human)	1	0.00 ± 0.00	0.00 ± 0.24	1.08* ± 0.07	0.43* ± 0.09	0.50 ± 0.24	
	4	0.70 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00	
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66	
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66	
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.48	
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06	

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^7 $TCID_{50}$/ml for human coronavirus and 5.6×10^7 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

Table 2 Log_{10} reduction of viruses on plastic coupons impregnated (5% or 10%) with zeolite powder (containing 6.5% copper, 3.5% silver ions)

Virus	Time (h)	Positive control[a]	5% Zeolite (w/w)	10% Zeolite (w/w)
Coronavirus 229E	1	0.22 ± 0.51	0.93 ± 0.05	0.80 ± 0.00
	4	0.50 ± 0.61	0.52 ± 0.47	0.44 ± 0.24
	24	0.67 ± 0.61	1.84* ± 0.20	1.77* ± 0.24
Feline calicivirus	1	0.04 ± 0.03	0.25* ± 0.06	0.67* ± 0.14
	4	0.17 ± 0.08	0.64* ± 0.19	0.96 ± 1.45
	24	0.40 ± 0.32	3.84 ± 1.02	5.05* ± 0.21

The experiment was conducted in triplicate at room temperature. The original titer was 4.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.0×10^6 PFU/ml for feline calicivirus. The ± indicates the standard deviation for the triplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Plastic coupons without zeolite

reductions for feline calicivirus were greater, including a 3.84-log_{10} reduction on the 5% Ag/Cu-zeolite coupons and a 5.05-log_{10} reduction on the 10% Ag/Cu-zeolite coupons after 24 h.

Discussion

To date, there have been no detailed studies of the interaction between heavy metals and viruses. Viruses that contain sulfhydryl termini may bind silver, interfering with viral replication (Davies and Etris 1997). Silver may also modify the adsorption of viruses to host cells (Tzagoloff and Pratt 1964). Thurman and Gerba (1989) suggested that viral inactivation might not require a metabolic process. For instance, the virus may be immobilized to a surface, the host-cell receptor may be blocked, or the nucleic acid within the viral capsid may be inactivated.

Copper is toxic to most microorganisms at higher concentrations, possibly due to the blocking of functional groups on proteins and the inactivation of enzymes (Faunder et al. 2004). Zinc oxide produces an active oxygen species at its surface that has a similar oxidative effect to hydrogen peroxide when it dissociates. This may damage the viral capsid and allow more metal ions inside the virus.

Unlike the respiratory disease caused by coronavirus 229E, FIPV causes gastrointestinal symptoms. The fact that Ag/Cu zeolite is effective against two substantially different coronaviruses suggests that it may also be effective in reducing the SCoV which causes severe respiratory disease, but which may also have a gastrointestinal component and is shed in the feces for greater than 10 weeks (Leung et al. 2003). The Ag/Cu zeolite was also effective against the nonenveloped feline calicivirus whose physical properties differ greatly from the enveloped coronaviruses.

Zeolite powders containing antiviral heavy metals have many potential applications. They may be added to materials such as plastics, paints, and synthetic fabrics (Quintavalla and Vicini 2002; Takai et al. 2002), and may be bonded to surfaces such as stainless steel (Bright et al. 2002; Cowan et al. 2003; Rusin et al. 2003). The effectiveness of the Ag/Cu zeolite against substantially different viruses appears promising for its potential use in applications to reduce environmental contamination of fomites by viral pathogens and thus the spread of diseases. Additional tests utilizing zeolites containing copper ions alone or in combination with various metals against other disparate viruses are needed.

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References

Anita, R., Rogues, R. R., Kuela, J. C., & Bengtsson, C. T. (2008). The role of evolution in the emergence of infectious diseases. *Nature, 426*, 658–661.

Barker, J., Stevens, D., & Bloomfield, S. F. (2001). Spread and prevention of some common viral infections in community facilities and domestic homes. *Journal of Applied Microbiology, 91*, 7–21.

Bidawid, S., Malik, N., Adegunrin, O., Sattar, S. S., & Farber, J. M. (2003). A feline kidney cell line-based plaque assay for feline calicivirus, a surrogate for Norwalk virus. *Journal of Virological Methods, 107*, 163–167.

Bright, K. R., Gerba, C. P., & Rusin, P. A. (2002). Rapid reduction of *Staphylococcus aureus* populations on stainless steel surfaces by zeolite ceramic coatings containing silver and zinc ions. *The Journal of Hospital Infection, 52*, 307–309.

Centers for Disease Control and Prevention. (2003). Revised U.S. surveillance case definition for severe acute respiratory syndrome (SARS) and update on SARS cases–United States and Worldwide, December 2003. *Morbidity and Mortality Weekly Report, 52*, 1202–1206.

Centers for Disease Control and Prevention. (2006). Norovirus: Technical fact sheet. http://www.cdc.gov/ncidod/dvrd/revb/gastro/downloads/noro-factsheet.pdf. Accessed 22 September 2008.

Chu, C. M., Cheng, V. C. C., Hung, I. F. N., Chan, K. S., Tang, B. S. F., Tsang, T. H. F., et al. (2005). Viral load distribution in SARS outbreak. *Emerging Infectious Diseases, 11*, 1882–1886.

Clay, S., Maherchandani, S., Malik, Y. S., & Goyal, S. M. (2006). Survival on uncommon fomites of feline calicivirus, a surrogate of noroviruses. *American Journal of Infection Control, 34*, 41–43.

Cowan, M. M., Abshire, K. Z., Houk, S. L., & Evans, S. M. (2003). Antimicrobial efficacy of a silver-zeolite matrix coating on stainless steel. *Journal of Industrial Microbiology & Biotechnology, 30*, 109–106.

Davies, R. J., & Bain, S. F. (1997). Development and functions of silver in water-purification and disease-control. *Catalysis Today, 36*, 109–114.

Doultree, J. C., Druce, J. D., Birch, C. J., Bowden, D. S., & Marshall, J. A. (1999). Inactivation of feline calicivirus, a Norwalk virus surrogate. *The Journal of Hospital Infection, 41*, 51–57.

Dowell, S. F., Simmerman, J. M., Erdman, D. D., Wu, J. S. J., Chaovavanich, A., Jarasil, M., et al. (2004). Severe acute respiratory syndrome coronavirus on hospital surfaces. *Clinical Infectious Diseases, 39*, 652–657.

Duan, S. M., Zhao, X. S., Wen, R. F., Huang, J. J., Pi, G. H., Zhang, S. X., et al. (2003). Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation. *Biomedical and Environmental Sciences, 16*, 246–255.

Evans, H. S., Madden, P., Douglas, C., Adak, G. K., O'Brien, S. J., Djuretic, J., et al. (1998). General outbreaks of infectious intestinal disease in England and Wales: 1995 and 1996. *Communicable Disease and Public Health, 1*, 165–171.

Fankhauser, R. L., Monroe, S. S., Noel, J. S., Ando, T. A., & Glass, R. I. (2002). Epidemiologic and molecular trends of Norwalk-like viruses associated with outbreaks of gastroenteritis in the United States. *The Journal of Infectious Diseases, 186*, 1–7.

Faundez, G., Troncoso, M., Navarrete, P., & Figueroa, G. (2004). Antimicrobial activity of copper surfaces against suspensions of *Salmonella enterica* and *Campylobacter jejuni*. *BMC Microbiology, 4*, 19.

Jiang, X., Wang, M., Wang, K., & Estes, M. K. (1993). Sequence and genomic organization of Norwalk virus. *Virology, 195*, 51–61.

Ksiazek, T. G., Erdman, D., Goldsmith, C. S., Zaki, S. R., Peret, T., Emery, S., et al. (2003). A novel coronavirus associated with severe acute respiratory syndrome. *The New England Journal of Medicine, 348*, 1953–1966.

Kwakye-Awuah, B., Williams, C., Kenward, M. A., & Radecka, I. (2008). Antimicrobial action and efficiency of silver-loaded zeolite X. *Journal of Applied Microbiology, 104*, 1516–1524.

Leung, W. K., To, K. F., Chan, P. K., Chan, H. L., Wu, A. K., Lee, N., et al. (2003). Enteric involvement of severe acute respiratory syndrome-associated coronavirus infection. *Gastroenterology, 125*, 1011–1017.

Lopman, B. A., Reacher, M. H., van Duijnhoven, Y., Hanon, F. X., Brown, D., & Koopmans, M. (2003). Viral gastroenteritis outbreaks in Europe, 1995–2000. *Emerging Infectious Diseases, 9*, 90–96.

Mead, P. S., Slutsker, L., Dietz, V., McCaig, L. F., Bresee, J. S., Shapiro, C., et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases, 5*, 607–625.

Myint, S. H. (1994). Human coronaviruses—A brief review. *Reviews in Medical Virology, 4*, 35–46.

Navas-Martin, S., & Weiss, S. (2004). Coronavirus replication and pathogenesis: Implications for the recent outbreak of severe acute respiratory syndrome (SARS), and the challenge for vaccine development. *Journal of Neurovirology, 10*, 75–85.

Payment, P., & Trudel, M. (1993). Isolation and identification of viruses. In P. Payment & M. Trudel (Eds.), *Methods and techniques in virology* (pp. 32–33). New York: Marcel Dekker.

Poutanen, S. M., Low, D. E., Henry, B., Finkelstein, S., Rose, D., Green, K., et al. (2003). Identification of severe acute respiratory syndrome in Canada. *The New England Journal of Medicine, 348*, 1995–2005.

Quintavalla, S., & Vicini, L. (2002). Antimicrobial food packaging in meat industry. *Meat Science, 62*, 373–380.

Rusin, P., Bright, K., & Gerba, C. (2003). Rapid reduction of *Legionella pneumophila* on stainless steel with zeolite coatings containing silver and zinc ions. *Letters in Applied Microbiology, 36*, 69–72.

Skerikà, M. I., & Appleton, H. (1998). Feline calicivirus as a model system for heat inactivation studies of small round structured viruses in shellfish. *Epidemiology and Infection, 121*, 401–407.

Smid, B., Valicek, L., Rodak, L., Stepanek, L., & Jurak, E. (1991). Rabbit haemorrhagic disease: An investigation of some properties of the virus and evaluation of an inactivated vaccine. *Veterinary Microbiology, 26*, 77–85.

Takai, K. T., Ohtsuka, T., Senda, Y., Nakao, M., Yamamoto, K., Matsuoka-Iseji, J., et al. (2002). Antibacterial properties of antimicrobial-finished textile products. *Microbiology and Immunology, 46*, 75–81.

Thurman, R. B., & Gerba, C. P. (1989). The molecular mechanisms of copper and silver ion disinfection of bacteria and viruses. *CRC Critical Reviews in Environmental Control, 18*, 295–315.

Tsugodoff, H., & Pratt, D. (1964). The initial steps in infection with coliphage MS1. *Virology, 24*, 372–380.

Watanabe, Y., Miyata, H., & Sato, H. (1989). Inactivation of laboratory animal RNA-viruses by physicochemical treatment. *Jikken Dobutsu, 38*, 305–311.

Widdowson, M. A., Sulka, A., Bulens, S. N., Beard, R. S., Chaves, S. S., Hammond, R., et al. (2005). Norovirus and foodborne disease, United States, 1991–2000. *Emerging Infectious Diseases, 11*, 95–102.

World Health Organization. (2004). *WHO guidelines for the global surveillance of severe acute respiratory syndrome (SARS) Updated recommendations October 2004*. New Delhi, India: Department of Communicable Disease Surveillance and Response, Regional Office for South-East Asia, World Health Organization.

Sciessent

Coronavirus (229E) White Paper

Agion Antimicrobial Efficacy Against Coronavirus is Tested and Published

The technology is deployed in the EU, Canada and United States in FDA cleared N95 respirator

February 10, 2020

The novel coronavirus (nCoV) outbreak in China has prompted several inquiries to Sciessent regarding the ability of Agion Antimicrobial to inactivate viruses. This white paper summarizes some university and government research previously completed on the antiviral properties of Agion.

Initial Research

The first half of the 2000's was marked by viral outbreaks that included H5N1 avian influenza, norovirus on cruise ships and the SARS coronavirus. Sciessent (formerly Agion Technologies) engaged with university researchers, industry partners and government organizations to investigate the ability of Agion to inactivate viruses. At the time the Chinese Center for Disease Control was looking for approaches to control the coronavirus and evaluated the Agion powder for efficacy. Around the same time Sciessent began working with Prof. Charles Gerba at the University of Arizona and to evaluate antiviral properties of Agion.

A Note on Terminology

Viruses are not living organisms; they must enter a living cell to multiply. Therefore, antiviral agents are said to "inactivate" viruses, not "kill" them.

Test Results

Chinese CDC (2003)

- Complete inactivation of SARS coronavirus in 2 hours
- *VERO E6 cell substrate, using virus CPE method*

University of Arizona (2004)

- 90% reduction of human coronavirus 229E in 1 hour
- 99% reduction of human coronavirus 229E in 2 hours
- 99.999% reduction of human coronavirus 229E in 24 hours
- *TCID50 technique, monitoring MRC-5 cell monolayers for cytopathic effects*

Chinese Academy of Agricultural Sciences (2006)

- 99% reduction of H5N1 avian influenza in 10 minutes
- *Klein-Defors suspension eradication test*

Published Research

A portion of the above results were published by Professor Gerba and his team in the peer-reviewed scientific journal *Food and Environmental Virology*:

> Assessment of the Antiviral Properties of Zeolites Containing Metal Ions.
> Food Environ Virol (2009) 1:37–41
>
> Abstract
>
> The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-log10 reduction within 24 h. It was also the most effective (>3.18-log10) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-log10 and >3.8-log10 reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.
>
> *Note: Springer Nature is making Coronavirus research free, including the above article.*

Agion in Polyester Fiber

During this time Sciessent worked with Foss Manufacturing (now Foss Performance Materials) to develop a polyester fiber with Agion embedded into the fiber itself. The fiber, named Fosshield, was incorporated into N95 respirator media as an approach to limit contamination of the respirator by the wearer or those around them. Further antiviral efficacy testing was performed on the respirator media construction.

N95 Respirator Media Test Results

- 99.98% reduction of coronavirus in 4 hours*
- 99.6% reduction of adenovirus in 1 hour*
- 99.999% reduction of haemophilus influenzae in 1 hour*
- 99.8% reduction of feline calicivirus (norovirus surrogate) in 4 hours*

**Results based on testing of samples containing Agion Antimicrobial*

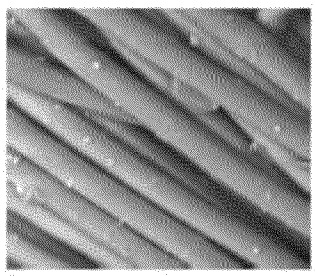
Once proven, the media was manufactured by Nexera Medical into an N95 respirator, which underwent extensive testing and was submitted to the FDA in 2009. The Nexera Spectrashield surgical respirator was cleared by NIOSH and received a 510(k) from the Food and Drug Administration in 2011 and has since been cleared in Canada and the European Union.

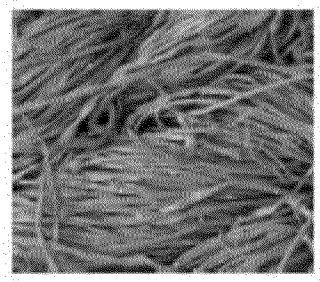
Approved claims for the European Union:

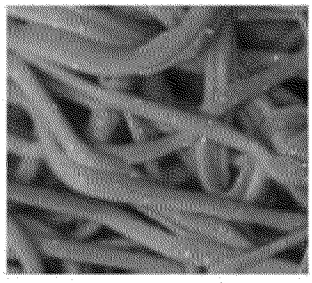
http://www.nexeramed.com/nfiles/news_110711_1.php

Approved claims for Canada:

http://www.nexeramed.com/cfiles/regulatory.php?region=CA







Application Options

Agion is a versatile material that can be mixed into coatings, compounded into plastics, and applied to textiles using several processes:

Topical – Fastest and most versatile

- Pad/Dry/Cure
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- Melt blown nonwoven
- Spunbond nonwoven

Contacts

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Fosshield: http://www.fossom.com/technology/fosshield.php

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Gerba

Assessment of the Antiviral properties of Zeolites Containing Metal Ions

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ORIGINAL PAPER

Assessment of the Antiviral Properties of Zeolites Containing Metal Ions

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Abstract The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-$\log_{10}$ reduction within 24 h. It was also the most effective (>3.18-$\log_{10}$) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-$\log_{10}$ and >3.8-$\log_{10}$ reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.

Keywords Coronavirus · Calicivirus · Fomites · Antiviral · Copper · Silver

Introduction

By July of 2003, 8,098 probable cases of severe acute respiratory syndrome (SARS) resulting in 774 deaths had been reported to the World Health Organization (WHO) from 29 countries on five continents (Centers for Disease Control and Prevention 2003; World Health Organization 2004). A novel coronavirus, SARS coronavirus (SCoV) was isolated from patients (Ksiazek et al. 2003; Navas-Martin and Weiss 2004). Before the identification of SCoV, two coronaviruses were known to infect humans, strains 229E and OC43 (Navas-Martin and Weiss 2004). These cause mild, self-limiting, upper respiratory tract infections (Myint 1994) and belong to the Group I and Group II coronaviruses, respectively. SCoV possesses characteristics specific to all three coronavirus groups (Navas-Martín and Weiss 2004), but is not closely related to any (Poutanen et al. 2003). It is apparently an animal virus that recently adapted to cross the species barrier, allowing for human-to-human transmission (Antia et al. 2003).

Human norovirus (NoV) causes illness in an estimated 23 million people in the United States each year, resulting in 50,000 hospitalizations and 310 deaths (Mead et al. 1999). It has been suggested that NoV may be the leading cause of foodborne illness in the United States (Widdowson et al. 2005), responsible for approximately 66% of all cases with known etiologies (Mead et al. 1999) and at least 50% of all foodborne outbreaks of gastroenteritis (Centers for Disease Control and Prevention 2006). NoV was identified in 93% of nonbacterial gastroenteritis outbreaks by the Centers for Disease Control and Prevention (CDC) between 1997 and 2000 in the United States (Fankhauser et al. 2002). Similarly, surveillance by the Foodborne Viruses in Europe network found that NoV was responsible for greater than 85% of all nonbacterial gastroenteritis outbreaks from 1995 to 2000 (Lopman et al. 2003).

Nonenveloped viruses are typically more resistant to environmental conditions and the action of antimicrobials

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than enveloped viruses (Watanabe et al. 1989; Barker et al. 2001). Feline calicivirus has been found to persist for up to 28 days in a dry environment at room temperature (Doultree et al. 1999). Also, in a study by Smid et al. (1991), rabbit hemorrhagic disease virus (also a calicivirus) survived for at least 105 days in a dried state at room temperature. Viruses that cause symptoms such as vomiting or diarrhea are likely to contaminate the environment. In one study, 607 of 680 (89%) norovirus outbreaks were linked to person-to-person transmission (Evans et al. 1998) that included poor hand hygiene as well as surface-to-surface transmission (Barker et al. 2001). Also, successive outbreaks of norovirus infections in passengers on cruise ships on separate trips have strongly implicated environmental contamination (Barker et al. 2001). Enveloped viruses are typically less stable in the environment, yet the SCoV is able to survive on fomites for up to 96 h (Duan et al. 2003). The transmission of SCoV is believed to be multifactorial, with evidence from previous outbreaks suggestive of at least some role for contaminated fomites in the transmission of the virus (Dowell et al. 2004; Chu et al. 2005).

Zeolite (sodium aluminosilicate) powders (AgION Technologies, Wakefield, MA, USA) form porous crystals. Metal ions may reside within these pores and zeolites can act as ion exchangers, exchanging metal ions for other cations in the environment. Although the effect of metal-zeolites has been documented in numerous studies with bacteria (Bright et al. 2002; Takai et al. 2002; Cowan et al. 2003; Rusin et al. 2003; Kwakye-Awuah et al. 2008), the use of zeolite powders containing heavy metal ions to reduce coronaviruses and caliciviruses has not been previously reported. This paper describes the antiviral effect of suspensions of zeolite powders amended with silver (Ag), copper (Cu), and zinc (Zn) ions in phosphate-buffered saline against human coronavirus 229E and feline infectious peritonitis virus (FIPV; feline coronavirus). This report also includes tests of the survival of human coronavirus 229E, FIPV, and feline calicivirus on the surfaces of plastics with zeolite containing Ag and Cu ions incorporated into the plastic.

Human coronavirus 229E and FIPV were employed in this study as surrogates for other coronaviruses. Feline calicivirus was also included as a surrogate for NoV. There is currently no practical method for propagating human NoV in cell culture monolayers. Feline calicivirus, on the other hand, grows readily in cell culture. It is in the same family as human NoV and is commonly used as a NoV surrogate in experiments (Slomka and Appleton 1998; Clay et al. 2006) because of its biochemical and genetic similarities to NoV (Jiang et al. 1993).

Materials and Methods

Virus Preparation

Human coronavirus strain 229E (ATCC #VR-740) was obtained from the American Type Culture Collection (ATCC, Manassas, VA, USA). It was maintained on MRC-5 (fetal human lung fibroblast, ATCC #CCL-171) cell line monolayers with minimal essential medium (MEM, modified with Earle's salts, Irvine Scientific, Santa Ana, CA, USA) containing 2% fetal bovine serum (FBS, Hyclone, Logan, UT, USA) at an incubation temperature of 35°C with 5% CO_2. Coronavirus 229E replicates better at this temperature than at 37°C. Feline infectious peritonitis virus (FIPV; ATCC #VR-990) and feline calicivirus strain F-9 (ATCC #VR-782) were maintained in the same manner on CRFK (Crandell Reese feline kidney, ATCC #CCL-94) cell line monolayers.

Viruses were purified by centrifugation (750×*g*) to remove cell debris followed by polyethylene glycol (9% PEG, 0.5 mol/l NaCl) precipitation. Viral titrations were performed using the Reed-Muench method (Payment and Trudel 1993) to determine the tissue culture infectious dose that affected 50% of the cultures ($TCID_{50}$).

Metal-Zeolite Powders in Suspension

Coronavirus strains 229E and FIPV were added to Erlenmeyer flasks containing 30.0 ml of phosphate buffered saline (PBS, pH 7.4; Sigma-Aldrich, St. Louis, MO, USA) with 10.0 mg of suspended zeolite test powder [either unamended powder, 20.0% Ag (w/w), 3.5% Ag/6.5% Cu, or 0.6% Ag/14% Zn/80% ZnO] (AgION Technologies, Wakefield, MA, USA). Positive control flasks without zeolite powder were also included. All experiments were performed in duplicate.

The positive control flasks (without zeolite powders) were sampled immediately ($t = 0$ h) by removing 1.0 ml from each flask and placing it into 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA). The 2.0 ml volumes were mixed thoroughly and placed into 4.0 ml of PBS (pH 7.4). All test flasks were then placed on an orbital shaker (200 rpm) at room temperature (23°C) and were sampled at 1, 4, and 24 h in the manner described previously. All samples were frozen in 1.0 ml aliquots at −80°C. Frozen aliquots were subsequently assayed using the Reed-Muench $TCID_{50}$ method as before (Payment and Trudel 1993).

Plastics with Incorporated Metal-Zeolites

Plastic coupons (5 cm by 5 cm) with either 5 or 10% (w/w) zeolite (containing 3.5% Ag and 6.5% Cu ions) incorporated

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (w/w), but with differing amounts [5 or 10% w/w] of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23 °C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

Statistical Analysis

A Student's *t* test was used to compare the viral counts recovered from the flasks containing test powder suspensions and test plastic coupons to those recovered from the positive controls.

Results

Metal-Zeolite Powders in Suspension

Amended zeolite powder suspensions were compared to determine which heavy metal combinations demonstrated the greatest activity against human coronavirus 229E. Unamended powder was used as a control to evaluate the effect of adsorption. The effect of Cu alone was undetermined. The results of the suspension tests are presented in Table 1. The results from the flasks containing zeolite control powder indicate that removal of virus was not due to adsorption by zeolite particles. Of the powder suspensions tested, the 3.5% Ag/6.5% Cu ion combination was the most efficacious, yielding a 1.08-$\log_{10}$ reduction of 229E after 1 h, a 2.06-$\log_{10}$ reduction after 4 h, and a >5.13-$\log_{10}$ reduction after 24 h of exposure. The greatest reductions observed for the other amended powders were following 24 h of exposure; nevertheless, the reductions at 24 h were not significantly greater ($P = 0.274$) than those after 4 h of exposure.

The 3.5% Ag/6.5% Cu combination was also effective (>3.18-$\log_{10}$ reduction) against FIPV within 4 h; however, neither of the other formulations was effective against FIPV, even after 24 h of exposure.

Plastics with Incorporated Metal-Zeolites

The results for the virus survival on the plastics with incorporated Ag/Cu-zeolite are shown in Table 2. Significant reductions were observed for coronavirus 229E on the Ag/Cu-zeolite plastic coupons after 24 h of exposure with a 1.84-$\log_{10}$ and a 1.77-$\log_{10}$ reduction achieved on the 5% and 10% (wt/wt) zeolite coupons, respectively. The

Table 1 Log_{10} reduction of coronaviruses after exposure to zeolite test powders amended with heavy metals

Virus	Time (h)	Positive control[a]	Zeolite control[b]	Amended zeolite powder (w/w)		
				3.5% Ag 6.5% Cu	20% Ag	0.6% Ag 14% Zn 80% ZnO
229E (human)	1	0.00 ± 0.00	0.00 ± 0.24	1.08* ± 0.07	0.43* ± 0.09	0.50 ± 0.34
	4	0.70 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.48
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^6 $TCID_{50}$/ml for human coronavirus and 5.6×10^5 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (w/w), but with differing amounts (5 or 10% w/w) of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23 °C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

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Plastics with Incorporated Metal-Zeolites

The results for the virus survival on the plastics with incorporated Ag/Cu-zeolite are shown in Table 2. Significant reductions were observed for coronavirus 229E on the Ag/Cu-zeolite plastic coupons after 24 h of exposure with a 1.84-$\log_{10}$ and a 1.77-$\log_{10}$ reduction achieved on the 5% and 10% (wt/wt) zeolite coupons, respectively. The

Table 1 $\log_{10}$ reduction of coronaviruses after exposure to zeolite test powders amended with heavy metals

Virus	Time (h)	Positive control[a]	Zeolite control[b]	Amended zeolite powder (w/w)		
				3.5% Ag 6.5% Cu	20% Ag	0.6% Ag 14% Zn 80% ZnO
229E (human)	1	0.00 ± 0.00	0.00 ± 0.24	1.08* ± 0.07	0.43* ± 0.09	0.50 ± 0.24
	4	0.70 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.48
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^6 $TCID_{50}$/ml for human coronavirus and 5.6×10^5 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

Table 2 Log_{10} reduction of viruses on plastic coupons impregnated (5% or 10%) with zeolite powder (containing 6.5% copper, 3.5% silver ions)

Virus	Time (h)	Positive control[a]	5% Zeolite (w/w)	10% Zeolite (w/w)
Coronavirus 229E	1	0.22 ± 0.51	0.93 ± 0.05	0.80 ± 0.00
	4	0.50 ± 0.61	0.52 ± 0.47	0.44 ± 0.24
	24	0.67 ± 0.61	1.84* ± 0.20	1.77* ± 0.24
Feline calicivirus	1	0.04 ± 0.08	0.25* ± 0.06	0.67* ± 0.14
	4	0.17 ± 0.08	0.64* ± 0.19	0.96 ± 1.45
	24	0.40 ± 0.32	3.84 ± 1.02	5.05* ± 0.21

The experiment was conducted in triplicate at room temperature. The original titer was 4.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.0×10^6 PFU/ml for feline calicivirus. The ± indicates the standard deviation for the triplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Plastic coupons without zeolite

reductions for feline calicivirus were greater, including a 3.84-log_{10} reduction on the 5% Ag/Cu-zeolite coupons and a 5.05-log_{10} reduction on the 10% Ag/Cu-zeolite coupons after 24 h.

Discussion

To date, there have been no detailed studies of the interaction between heavy metals and viruses. Viruses that contain sulfhydryl termini may bind silver, interfering with viral replication (Davies and Etris 1997). Silver may also modify the adsorption of viruses to host cells (Tzagoloff and Pratt 1964). Thurman and Gerba (1989) suggested that viral inactivation might not require a metabolic process. For instance, the virus may be immobilized to a surface, the host-cell receptors may be blocked, or the nucleic acid within the viral capsid may be inactivated.

Copper is toxic to most microorganisms at higher concentrations, possibly due to the blocking of functional groups on proteins and the inactivation of enzymes (Fraunder et al. 2004). Zinc oxide produces an active oxygen species at its surface that has a similar oxidative effect to hydrogen peroxide when it dissociates. This may damage the viral capsid and allow more metal ions inside the virus.

Unlike the respiratory disease caused by coronavirus 229E, FIPV causes gastrointestinal symptoms. The fact that Ag/Cu zeolite is effective against two substantially different coronaviruses suggests that it may also be effective in reducing the SCoV which causes severe respiratory disease, but which may also have a gastrointestinal component and is shed in the feces for greater than 10 weeks (Leung et al. 2003). The Ag/Cu zeolite was also effective against the nonenveloped feline calicivirus whose physical properties differ greatly from the enveloped coronaviruses.

Zeolite powders containing antiviral heavy metals have many potential applications. They may be added to materials such as plastics, paints, and synthetic fabrics (Quintavalla and Vicini 2002; Takai et al. 2002), and may be bonded to surfaces such as stainless steel (Bright et al. 2002; Cowan et al. 2003; Rusin et al. 2003). The effectiveness of the Ag/Cu zeolite against substantially different viruses appears promising for its potential use in applications to reduce environmental contamination of fomites by viral pathogens and thus the spread of diseases. Additional tests utilizing zeolites containing copper ions alone or in combination with various metals against other disparate viruses are needed.

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References

Antia, R., Regoes, R. R., Koella, J. C., & Bergstrom, C. T. (2003). The role of evolution in the emergence of infectious diseases. *Nature, 426*, 658–661.

Barker, J., Stevens, D., & Bloomfield, S. F. (2001). Spread and prevention of some common viral infections in community facilities and domestic homes. *Journal of Applied Microbiology, 91*, 7–21.

Bidawid, S., Malik, N., Adegunin, O., Sattar, S. S., & Farber, J. M. (2003). A feline kidney cell line-based plaque assay for feline calicivirus, a surrogate for Norwalk virus. *Journal of Virological Methods, 107*, 163–167.

Bright, K. R., Gerba, C. P., & Rusin, P. A. (2002). Rapid reduction of *Staphylococcus aureus* populations on stainless steel surfaces by zeolite ceramic coatings containing silver and zinc ions. *The Journal of Hospital Infection, 52*, 307–309.

Centers for Disease Control and Prevention. (2003). Revised U.S. surveillance case definition for severe acute respiratory syndrome (SARS) and update on SARS cases–United States and Worldwide, December 2003. *Morbidity and Mortality Weekly Report, 52*, 1202–1206.

Centers for Disease Control and Prevention. (2006). Norovirus: Technical fact sheet. http://www.cdc.gov/ncidod/dvrd/revb/gastro/download/norov-factsheet.pdf. Accessed 22 September 2008.

Chu, C. M., Cheng, V. C. C., Hung, I. F. N., Chan, K. S., Tang, B. S. F., Tsang, T. H. F., et al. (2005). Viral load distribution in SARS outbreak. *Emerging Infectious Diseases, 11*, 1882–1886.

Clay, S., Maherchandani, S., Malik, Y. S., & Goyal, S. M. (2006). Survival on uncommon fomites of feline calicivirus, a surrogate of noroviruses. *American Journal of Infection Control, 34*, 41–43.

Cowan, M. M., Abshire, K. Z., Houk, S. L., & Evans, S. M. (2003). Antimicrobial efficacy of a silver-zeolite matrix coating on stainless steel. *Journal of Industrial Microbiology & Biotechnology, 30*, 102–106.

Davies, R. L., & Etris, S. F. (1997). Development and functions of silver in water-purification and disease-control. *Catalysis Today, 36*, 107–114.

Doultree, J. C., Druce, J. D., Birch, C. J., Bowden, D. S., & Marshall, J. A. (1999). Inactivation of feline calicivirus, a Norwalk virus surrogate. *The Journal of Hospital Infection, 41*, 51–57.

Dowell, S. F., Simmerman, J. M., Erdman, D. D., Wu, J. S. J., Chaovavanich, A., Javali, M., et al. (2004). Severe acute respiratory syndrome coronavirus on hospital surfaces. *Clinical Infectious Diseases, 39*, 652–657.

Duan, S. M., Zhao, X. S., Wen, R. F., Huang, J. J., Pi, G. H., Zhang, S. X., et al. (2003). Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation. *Biomedical and Environmental Sciences, 16*, 246–255.

Evans, H. S., Madden, P., Douglas, C., Adak, G. K., O'Brien, S. J., Djuretic, J., et al. (1998). General outbreaks of infectious intestinal disease in England and Wales: 1995 and 1996. *Communicable Disease and Public Health, 1*, 165–171.

Fankhauser, R. L., Monroe, S. S., Noel, J. S., Ando, T. A., & Glass, R. I. (2002). Epidemiologic and molecular trends of Norwalk-like viruses associated with outbreaks of gastroenteritis in the United States. *The Journal of Infectious Diseases, 186*, 1–7.

Hernandez, G., Troncoso, M., Navarrete, P., & Figueroa, G. (2004). Antimicrobial activity of copper surfaces against suspensions of *Salmonella enterica* and *Campylobacter jejuni*. *BMC Microbiology, 4*, 19.

Jiang, X., Wang, M., Wang, K., & Estes, M. K. (1993). Sequence and genomic organization of Norwalk virus. *Virology, 195*, 51–61.

Ksiazek, T. G., Erdman, D., Goldsmith, C. S., Zaki, S. R., Peret, T., Emery, S., et al. (2003). A novel coronavirus associated with severe acute respiratory syndrome. *The New England Journal of Medicine, 348*, 1953–1966.

Kwakye-Awuah, B., Williams, C., Kenward, M. A., & Radecka, I. (2008). Antimicrobial action and efficiency of silver-loaded zeolite X. *Journal of Applied Microbiology, 104*, 1516–1524.

Leung, W. K., To, K. F., Chan, P. K., Chan, H. L., Wu, A. K., Lee, N., et al. (2003). Enteric involvement of severe acute respiratory syndrome-associated coronavirus infection. *Gastroenterology, 125*, 1011–1017.

Lopman, B. A., Reacher, M. H., van Duijnhoven, Y., Hanon, F. X., Brown, D., & Koopmans, M. (2003). Viral gastroenteritis outbreaks in Europe, 1995–2000. *Emerging Infectious Diseases, 9*, 90–96.

Mead, P. S., Slutsker, L., Dietz, V., McCaig, L. F., Bresee, J. S., Shapiro, C., et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases, 5*, 607–625.

Myint, S. H. (1994). Human coronaviruses—A brief review. *Reviews in Medical Virology, 4*, 35–46.

Navas-Martin, S., & Weiss, S. (2004). Coronavirus replication and pathogenesis: Implications for the recent outbreak of severe acute respiratory syndrome (SARS), and the challenge for vaccine development. *Journal of Neurovirology, 10*, 75–85.

Payment, P., & Trudel, M. (1993). Isolation and identification of viruses. In P. Payment & M. Trudel (Eds.), *Methods and techniques in virology* (pp. 32–33). New York: Marcel Dekker.

Poutanen, S. M., Low, D. E., Henry, B., Finkelstein, S., Rose, D., Green, K., et al. (2003). Identification of severe acute respiratory syndrome in Canada. *The New England Journal of Medicine, 348*, 1995–2005.

Quintavalla, S., & Vicini, L. (2002). Antimicrobial food packaging in meat industry. *Meat Science, 62*, 373–380.

Rusin, P., Bright, K., & Gerba, C. (2003). Rapid reduction of *Legionella pneumophila* on stainless steel with zeolite coatings containing silver and zinc ions. *Letters in Applied Microbiology, 36*, 69–72.

Skilton, M. J., & Appleton, H. (1998). Feline calicivirus as a model system for heat inactivation studies of small round structured viruses in shellfish. *Epidemiology and Infection, 121*, 401–407.

Smid, B., Vallicek, L., Rodak, L., Stepanek, J., & Jurak, E. (1991). Rabbit haemorrhagic disease: An investigation of some properties of the virus and evaluation of an inactivated vaccine. *Veterinary Microbiology, 26*, 77–85.

Takai, K. T., Ohtsuka, T., Senda, Y., Nakao, M., Yamamoto, K., Matsuoka-Inaji, J., et al. (2002). Antibacterial properties of antimicrobial-finished textile products. *Microbiology and Immunology, 46*, 75–81.

Thurman, R. B., & Gerba, C. P. (1989). The molecular mechanisms of copper and silver ion disinfection of bacteria and viruses. *CRC Critical Reviews in Environmental Control, 18*, 295–315.

Tzagoloff, H., & Pratt, D. (1964). The initial steps in infection with coliphage M13. *Virology, 24*, 372–380.

Watanabe, Y., Miyata, H., & Sato, H. (1989). Inactivation of laboratory animal RNA-viruses by physicochemical treatment. *Jikken Dobutsu, 38*, 305–311.

Widdowson, M. A., Sulka, A., Bulens, S. N., Beard, R. S., Chaves, S. S., Hammond, R., et al. (2005). Norovirus and foodborne disease, United States, 1991–2000. *Emerging Infectious Diseases, 11*, 95–102.

World Health Organization. (2004). *WHO guidelines for the global surveillance of severe acute respiratory syndrome (SARS) Updated recommendations October 2004*. New Delhi, India: Department of Communicable Disease Surveillance and Response, Regional Office for South-East Asia, World Health Organization.

Sciessent

H5N1
Test Report

Redacted

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
& Animal Flu Key-point Open Lab
National Bird Flu Reference Lab of the Ministry of Agriculture

Test Result Certification

2006-1-15

Commissioned by: Beijing SR Science & Technology Co., Ltd. ([redacted])
The product for the test: Inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A)
The title of the test: The in vitro inactivation effect of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against bird influenza virus (H5N1)

Viral strain: H5N1 bird influenza virus
Test method: Refer to the attached Annexes, please.
The in vitro inactivation effect of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against bird influenza virus (H5N1)

Test result:

By adopting Klein-Defors Suspension and having made the 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml of inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) solutions acted on the H5 sub-type bird influenza virus suspension (with the proportion of 9:1) for 10min, the sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the virus in different dilute concentrations is 100%, 99%, 0, 0, 0 .

The sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the H5 sub-type bird influenza virus*

	Inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) (mg/ml)					
	200	100	20	10	4	2
The virus-sterilized & inactivated rate of inorganic antiseptic Zeomic AC10N against virus	100%	99%	0	0	0	0

*The result attests that after 10min action on bird influenza virus, the sterilized and inactivated rate of 200mg/ml inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the virus is 100%, within the range of which the effect to kill virus is conspicuous.

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
& Animal Flu Key-point Open Lab
National Bird Flu Reference Lab of the Ministry of Agriculture

This Test Report is valid to the supplied sample(s) only.

Test Report

Commissioned by: Beijing SR Science & Technology Co., Ltd.
Tell: 010-82133252
Fax: 010-82133282
Add: Room 1804 of Building No. 10, Sun Garden Resident Quarters, Haidian District, Beijing, China

Tested by: Harbin Veterinary Research Institute of China Agricultural Scientific Academy & Animal Flu Key-point Open Lab & National Bird Flu Reference Lab of the Ministry of Agriculture
Add: No. 427 Maisi Street, Nangang District, Harbin City, China
Tell: 0451-85935084

Jan. 2006

Interpretation

1. This Test Report holds true only for the result of the tested contents of the samples delivered for the test.
2. This Test Report would be invalidated if alteration, addition and deletion is found, as well as free from signature and official stamp.
3. Both of this Test Report and the name of this test and verification organization are disallowed to utilize as product label and for advertisement, commercial propaganda and appraisal of high-quality product etc.
4. This Test Report is in quadruplication, two copies are archived by each of the test organization and sample delivery organization respectively.

Add: No. 427 Marui Street, Nangang District, Harbin, China
Zip code: 150001
Tell: 0451-85935084

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
Animal Flu Key-point Open Lab of the Ministry of Agriculture
National Bird Flu Reference Lab of the Ministry of Agriculture

The in vitro inactivation effect of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against bird influenza virus (H5N1)

This laboratory has conducted the test for the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) delivered by Beijing SR Science & Technology Co., Ltd. for in vitro sterilization and inactivation of influenza virus. The Test Report for the tested result is as follows:

1. Stuff and means for the test

1.1 The product for the test

The inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) is Blue powdor, packed with 100g/bag and provided by Beijing SR Science & Technology Co., Ltd. Its lot number is AC0001.

1.2 Viral strain

The viral stain is H5N1 bird influenza virus in sub-type high pathogenicity, which is preserved by relying on Harbin Veterinary Research Institute of China Agricultural Scientific Academy & Animal Flu Key-point Open Lab & National Bird Flu Reference Lab of the Ministry of Agriculture.

1.3 Chick embryo

The Experimental Animal Center of Harbin Veterinary Research Institute of China Agricultural Scientific Academy provided the SPF chick embryo of 10-day's age.

1.4 Test preparation

1.4.1 Determination of virus EID_{50}

Inoculate the H5 sub-type bird influenza that is diluted by 10-time series into the SPF chick embryo of 10-day's age. Each degree of dilution is for 5 chick embryos (0.1ml/embryo), and then to determine the viral half infective dose (EID_{50}).

1.4.2 Preparation for the tested product—the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A)

In the test, first of all dissolve 1g of the inorganic antiseptics of [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) in 5ml sterilized normal saline to be made into 200mg/ml solution for future use.

1.4.3 Toxicity test for the chick embryo of the inorganic antiseptics of [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A)

Inoculate 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml solutions of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) into SPF chick embryo of 10-day's age respectively, and each dilution rate of the solution is for the inoculability of five chick embryos (0.1ml/embryo). Place the inoculated chick embryos in

the 37℃ incubator to cultivate them for 96h. Remove the chick embryo that has died within 24h, and write down the death information of the chick embryos.

1.5 Test for the sterilizing and inactivating rate of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the virus

Klein-Defors suspension method is to be adopted for the test of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) to sterilize and inactivate the high pathogenic bird influenza virus; Made the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) that is diluted with sterilized normal saline acted on the virus for a certain period, and then conduct 10-time series dilution of the mixed dilution in different dilution rates. Then, inoculate the mixed solution into the chick embryos and check the condition of the infected chick embryo.

1.5.1 Suspension sterilizing and inactivating test with Klein-Defors Method

First of all, mix the $10^{7.4}EID_{50}$ H5 sub-type bird influenza virus suspension with 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) respectively according to the proportion of 1:9; after 10min process under the temperature condition of 20±1℃, and then have the soak solution diluted with sterilizing normal saline by gradually increasing 10 times to turn out 10 dilution rates; each degree of dilution shall be used for the inoculation of 5 chick embryo (0.1ml/embryo); with regard to the samples in negative control group, sterilized normal saline is substituted for the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) and treated with the same method; inoculate the diluents into the SPF chick embryo of 10-dat age and each dilution rate is for the inoculability of 5 chick embryos (0.1ml/embryo). Place the inoculated chick embryos in the 37℃ incubator for cultivation, and write down the death information of the chick embryo. Remove the chick embryo that died within 24h, take out that died after 24h timely, and take off the entire ones from the incubator till 96h. Take out the allantoic fluid from the dead embryo one by one to perform hemagglutination (HA) test. It should be diagnosed infestation of chick embryo if the hemagglutination (HA) test assumes positive.

Calculate the infectious positive rate, content of EID_{50} in the samples and virus-sterilizing and inactivating rate of the chick embryos in both of the tested group and the control groups according to infectious result of the chick embryo by using the following equation:

The positive rate = the chick embryo quantity that assumes positive in hemagglutination/the quantity of inoculated chick embryos;

The logarithm for the content of EID50 in the samples = L - d (S - 0.5)

("L" is the logarithm of the minimum dilution multiple, "d" is the logarithmic difference among the degrees of dilution and "S" is the sum of the positive rate of various dilution series).

The sterilized and inactivated rate of the virus = (the content of EID_{50} in the control sample — the content of EID_{50} in the tested sample) / the content of EID_{50} in the control sample x100%.

2. Result

2.1 Determination of virus EID50

It's observed from Table 1 that after the H5 sub-type bird influenza virus is diluted by 10 times in series, having the diluted solution inoculated into the chick embryos of 10-day's age respectively, and each dilution rate of the solution is for 5 chick embryos (0.1ml/embryo), the test result shows that the half infective dose (EID_{50}) of the virus is $10^{7.5}EID_{50}$/0.1ml.

Table 1: Determination of H5 sub-type bird influenza virus EID_{50}

	10-time step-up dilution of H5 sub-type bird influenza virus solution									
	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	10^{-9}	10^{-10}
Infective condition of the chick embryos	5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5	0/5
EID_{50}/0.1ml	$10^{-8}EID_{50}$/0.1ml									

Note: The numerator is the quantity of the embryo hemagglutination (HA) activity, and the denominator is the quantity of inoculated embryo.

2.2 Toxicity test for the chick embryo applied with the tested product - the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A)

It's observed from Table 1 that after the 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml solution of the inorganic antiseptics [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) is inoculated into SPF chick embryos of 10-day's age respectively, and each dilution rate of the solution is for the inoculability of five chick embryos (0.1ml/embryo), the test result shows that the chick embryo is free from visual pathological change after the application of the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) within the dilution rate of the said tests.

Table 2: The maximum non-poisonous dosage of the inorganic antiseptic Zeomic AC10N to chick embryo

	Different dilution rate of the inorganic antiseptic Zeomic AC10N (mg/ml)					
	200	100	20	10	4	2
Death condition of the chick embryos (Piece)	0/5	0/5	0/5	0/5	0/5	0/5

Note: The numerator is the quantity of died embryos, and the denominator is the quantity of inoculated embryos.

2.3 The sterilizing and inactivating effect of the inorganic antiseptics [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against bird influenza virus

Having made the 200mg/ml, 100mg/ml, 20mg/ml, 10mg/ml, 4mg/ml and 2mg/ml of

Inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) solutions acted on the H5 sub-type bird influenza virus suspension (with the proportion of 9:1) for 10min, the sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the virus in different dilute concentrations is 100%, 99%, 0, 0, 0 and 0; for the results, refer to Table 3.

Table 3: The sterilized and inactivated rate of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) against the H5 sub-type bird influenza virus in different dilute concentrations

	Different dilute concentrations of the inorganic antiseptic [redacted] AC10N [redacted] Type AC Silver Copper Zeolite A) (mg/ml)					
	200	100	20	10	4	2
The virus-sterilized & inactivated rate of inorganic antiseptic Zeolite AC10N against virus	100%	99%	0	0	0	0

3. Conclusion

By adopting Klein-Defors Suspension and Infection Test method to allow the inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) to act directly on H5N1 sub-type bird influenza virus (with the proportion of 9:1) in vitro for 10min in different concentrations, so as to detect the sterilizing and inactivating effect of the inorganic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) on bird influenza virus in vitro. The result attests that after 10min action on bird influenza virus, the sterilized and inactivated rate of 200mg/ml inorganic antiseptic [redacted] AC10N ([redacted] Type AC Silver Copper Zeolite A) against the virus is 100%, within the range of which the effect to kill virus is conspicuous.

4. References

(1) Lab technical specification in Volume II of the "***Sterilizing Technical Specification***" 2002 - by the Ministry of Public Health

(2) "The Sterilizing & Inactivating Effect of 3-kind of Antiseptics on H5N1 & H9N2 Sub-type Bird Influenza Virus" from the "Collected Papers from the 11th Academic Seminar of the Bird Disease Lodge of the China Animal Husbandry Veterinarian Academy 2002, 10:150 – by Li Yanhua, Tian Guobin, Feng Juyan etc.

Harbin Veterinary Research Institute of China Agricultural Scientific Academy
Animal Flu Key-point Open Lab of the Ministry of Agriculture
National Bird Flu Reference Lab of the Ministry of Agriculture

Jan. 15, 2006

Sciessent

SARS
Test Report

[redacted]-AJ10N
无机抗菌剂体外灭活 SARS 病毒试验总结

试验设计负责人：段淑敏
试验参加者：[illegible]、赵新生、温瑞福、黄晶晶
试验时间：2003 年 9 月~2003 年 10 月
试验单位：中国疾病预防控制中心病毒病预防控制所
试验资料联系电话：010-63536459
委托单位：北京长城永毅科技发展有限公司

中国疾病预防控制中心病毒病预防控制所
2003 年 10 月 7 日

[redacted]-AJ10N 无机抗菌剂体外灭活 SARS 病毒试验总结

摘要：

在非洲绿猴肾传代细胞（VERO E6）培养内，采用病毒(CPE)法，检测[redacted]AJ10N 无机抗菌剂体外对 SARS 病毒的灭活效果，试验结果表明该材料在室温作用 6 小时以上对 SARS 病毒的有一定的灭活作用。

一、 试验目的

检测[redacted]AJ10N 无机抗菌剂在室温情况下与 SARS 病毒作用不同的时间，是否有灭活 SARS 病毒的作用，为加快灭活 SARS 病毒材料的筛选进度提供试验依据。

二、 试验材料

1. 验证材料：

[redacted]-AJ10N 无机抗菌剂：呈白色粉末，每袋 10 克， 由北京长城永毅科技发展有限公司提供

2. 阳性对照药物：

注射用更昔洛韦：批号 020802 由湖北科益药业股份有限公司提供。

3. 病毒：

SARS-COV-P11 冠状病毒分离株（SARS 病人血清 11 号标本）由佑安医院提供，本室分离鉴定。

SARS-COV-P8 冠状病毒分离株 由病毒病预防控制所出血热室（李德新教授提供）。

4. 细胞：

非洲绿猴肾传代细胞（VERO E6），由本室提供。

5. Eagle's 细胞培养维持液等试验材料，均由本室提供。

三、实验方法

1. [redacted]-AJ10N 无机抗菌剂对 VERO E6 细胞的毒性测定

在 VERO E6 细胞培养内，采用细胞形态变化（CPE）法，用 Reed-Muench 法，计算药物半数中毒浓度（TD_{50}）和最大无毒浓度（TD_0）。

[redacted]-AJ10N 无机抗菌剂预处理：

将 6000μg/ml 的 [redacted]-AJ10N 无机抗菌剂放入一容器内，用 Eagle's 细胞维持液稀释后，放在磁力搅拌器上（温度为室温），在搅拌 2 小时、4 小时、6 小时的时候，分别取样进行稀释，即 6000μg/ml~187.5μg/ml，接种 VERO E6 细胞 96 孔培养板。

细胞形态变化 CPE 法：

VERO E6 细胞以 40 万/ml 浓度接种 96 孔培养板，37℃、5%CO_2 培养 24 小时，至细胞单层，分别加入预处理好的 [redacted]-AJ10N 无机抗菌剂，浓度为 6000μg/ml~187.5μg/ml，阳性对照药物倍比稀释为 6000μg/ml~187.5μg/ml，每浓度接种 4 孔，每孔 100μl。同时设正常细胞对照。置 37℃、5% CO_2 培养 5~7 天，每 24 小时在倒置显微镜下观察细胞形态变化，记录细胞形态变化（CPE）：以 25%以下变化为 +，26%~50%变化为 ++，51%~75%为 +++，76%~100%变化为 ++++，试验重复三次。

2. 在 VERO E6 细胞培养内对 SARS-COV-P11 分离鉴定

SARS-COV-P11（SARS 病人 11 号血清分离）：

VERO E6 细胞以每毫升 40 万浓度接种试管，37℃ 5%CO_2 培养 24 小时，弃掉培养液，每管加入 SARS 病人血清 0.2ml，37℃转鼓培养 5 小时后，加入维持液 1ml，同时设正常细胞对照，37℃转鼓培养 5~7 天，细胞出现 CPE 变化后，采用 PCR 的方法检测冠状病毒，11 号标本 PCR 阳性，确定为冠状病毒分离株，用终末稀释法纯化病毒 2 次，PCR 检测，SARS 病毒 S 基因测序仍为阳性，经免疫荧光测定双份 SARS 病人血清，IgM 阳性，IgG4 倍升高，确定为冠状病毒。采用病毒 CPE 法测定其效价。

在 VERO E6 细胞培养内对 SARS-COV-P1 和 SARS-COV-P8 毒株毒力的测定

病毒 CPE 法：

VERO E6 细胞以每毫升 40 万浓度接种 96 孔培养板，37℃ 5%CO_2 培养 24 小时，去掉培养液，分别将 2 株病毒稀释，稀释成 10^{-1} ~ 10^{-8}，8 个浓度，每浓度 4 孔，每孔 100μl，设正常细胞对照，37℃ 5%CO_2 培养 5~7 天，每 24 小时

在倒置显微镜下观察记录细胞形态变化（CPE）：以25%以下变化为“+”，26%~50%变化为“++”，51%~75%为“+++”，76%~100%变化为“++++”，用Reed-Muench法，计算病毒半数感染浓度$TCID_{50}$。

3. [redacted]-AJ10N无机抗菌剂在VERO E6细胞培养内对SARS-COV-P11和SARS-COV-P8的灭活作用

试验目的：

在VERO E6细胞培养内，采用病毒细胞（CPE）法，观察不同浓度的[redacted]-AJ10N无机抗菌剂对SARS病毒的灭活作用，计算半数有效浓度（IC_{50}）和最小有效浓度（MIC）及治疗指数TI，判断药效。

100$TCID_{50}$SARS病毒与[redacted]-AJ10N无机抗菌剂预处理：

将2株100$TCID_{50}$SARS病毒稀释液分别与750μg/ml的[redacted]-AJ10N无机抗菌剂放在一容器内，在磁力搅拌器上（温度为室温），搅拌2小时、4小时、6小时分别取样进行稀释，即750μg/ml~11.7μg/ml，接种VERO E6细胞96孔培养板。

病毒CPE法

VERO E6细胞以40万/ml浓度接种96孔培养板，37℃ 5% CO_2孵箱培养24小时，细胞培养至单层，弃掉培养液。加入经SARS病毒与[redacted]AJ10N无机抗菌剂预处理的溶液，选用对细胞的最大无毒浓度（TD_0）2倍稀释7个浓度即为750μg/ml～11.7μg/ml，同时设预处理的[redacted]AJ10N无机抗菌剂对照，2倍稀释7个浓度即750μg/ml～5.9μg/ml，设阳性对照药物注射用更昔洛韦，药物选用对细胞的最大无毒浓度（TD_0）2倍稀释7个浓度即6000μg/ml～5.9μg/ml，将稀释好的药物分别加入细胞孔内，每浓度4孔，同时设正常细胞对照和病毒对照，置37℃ 5% CO_2培养箱培养5~7天，逐日在倒置显微镜下观察病毒CPE，以病毒对照出现+++ — ++++时结束试验，用Reed－Muench法，计算药物的半数有效浓度（IC_{50}）和最小有效浓度（MIC）及治疗指数（TI）判断药效，试验重复三次。

四、试验结果

预备试验结果：

[redacted]AJ10N无机抗菌剂对VERO E6细胞的毒性作用：

由北京长城永科技有限公司提供的[redacted]AJ10N无机抗菌剂和阳性对照药物注射用更昔洛韦在VERO E6细胞培养内，采用细胞形态变化（CPE）法。计算该材料的最大无毒浓度（TD_0）和半数中毒浓度（TD_{50}），以下试验结果为三次试验结果的均值。

1．[redacted]AJ10N无机抗菌剂对VERO E6细胞的毒性试验结果

验证材料：

[redacted]AJ10N无机抗菌剂：最大无毒浓度（TD_0）为750±0μg/ml，半数中毒浓度（TD_{50}）为1500±0μg/ml

阳性对照药物：

注射用更昔洛韦：最大无毒浓度（TD_0）为>6000±0μg/ml，半数中毒浓度（TD_{50}）为>6000±0μg/ml 。

2．在VERO E6细胞培养内对SARS-COV-P11、SARS-COV-P8毒力测定结果

SARS-COV-P11：半数感染量（$TCID_{50}$）为10^{-7}

SARS-COV-P8：半数感染量（$TCID_{50}$）为10^{-7}

正式试验结果

1．[redacted]AJ10N无机抗菌剂与SARS-COV-P11分别作用2小时、4小时、6小时后，在VERO E6细胞培养内检测灭活的效果，分别以IC50、MIC、TI和灭活%为指标（以下试验数据为三次试验结果的均值）

检测灭活的效果（以IC50、MIC、TI为指标）

验证材料：

[redacted]-AJ10N无机抗菌剂：

室温作用2小时：病毒CPE法，半数有效浓度（IC_{50}）为188±0μg/ml，最小有效浓度（MIC）为94±0μg/ml ，治疗指数（TI）为8。

室温作用4小时：病毒CPE法，半数有效浓度（IC_{50}）为188±0μg/ml，最小有效浓度（MIC）为94±0μg/ml ，治疗指数（TI）为8。

室温作用6小时：病毒CPE法，半数有效浓度（IC_{50}）为94±0μg/ml，最小有效浓度（MIC）为46.8±0μg/ml ，治疗指数（TI）为16。

检测灭活的效果（以灭活%为指标）

室温作用2小时：病毒CPE法，当[redacted]-AJ10N无机抗菌剂稀释浓度>375μ

g/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 4 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 6 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>188μg/ml 即可灭活 100%的 SARS 病毒，稀释为 94μg/ml 时可灭活 50%的 SARS 病毒，稀释为 46.8μg/ml 时可灭活 25%的 SARS 病毒。

阳性对照药物：

注射用更昔洛韦：CPE 法，药物半数有效浓度（IC_{50}）为 11.7±0μg/ml ，最小有效浓度（MIC）为 23.44±0μg/ml，治疗指数（TI）为 256。

2.[redacted]-AJ10N 无机抗菌剂与 SARS-COV- P8 作用 2 小时、4 小时、6 小时后，在 VERO E6 细胞培养内检测灭活的效果，分别以 IC50、MIC、TI 和灭活%为指标（以下试验数据为三次试验结果的均值）

检测灭活的效果（以 IC50、MIC、TI 为指标）

验证材料：

验证材料：

[redacted]-AJ10N 无机抗菌剂：

室温作用 2 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 4 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 6 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 94±0μg/ml，最小有效浓度（MIC）为 46.8±0μg/ml ，治疗指数（TI）为 16。

检测灭活的效果（以灭活%为指标）

室温作用 2 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 4 小时：病毒 CPE 法，当[redacted]-AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病

毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 6 小时：病毒 CPE 法，当 [redacted]AJ10N 无机抗菌剂稀释浓度>188μg/ml 即可灭活 100%的 SARS 病毒，稀释为 94μg/ml 时可灭活 50%的 SARS 病毒，稀释为 46.8μg/ml 时可灭活 25%的 SARS 病毒。

阳性对照药物：

注射用更昔洛韦：CPE 法，药物半数有效浓度（IC_{50}）为 11.7±0μg/ml ，最小有效浓度（MIC）为 23.44±0μg/ml，治疗指数（TI）为 256。

总　　结

由北京长城永毅科技发展有限公司提供的 [redacted]AJ10N 无机抗菌剂和阳性对照药物注射用更昔洛韦在 VERO E6 细胞培养内，采用病毒 CPE 法，在 2 株 SARS 病毒分离株上进行验证，试验结果表明 [redacted]AJ10N 无机抗菌剂和 SARS 病毒在室温作用 6 小时以上，对 SARS 病毒有一定的灭活作用。

试验设计负责人：段源敏

试验参加者：段源敏、赵新生、温瑞福、黄晶晶

试验日期：2003 年 9 月~2003 年 10 月

试验单位：中国疾病预防控制中心病毒病预防控制所

[redacted]

试验负责人联系电话：010-63536459

委托单位：北京长城永毅科技发展有限公司

中国疾病预防控制中心病毒病预防控制所

2003 年 10 月 7 日

Sciessent

Nexera Medical
Mask Utilizing Silver Zeolite Technology

K120244

NEXERA MEDICAL

JUL 5 2012

Section 5.0: 510(k) SUMMARY

510(k) Owner: NexEra Medical, Inc.
3343 West Commercial Blvd, Suite 103
Ft. Lauderdale, FL 33309

Contact: Paul Sallarulo, President CEO
Phone: 954-495-2020, x 2031
Fax: 954-491-7281

Establishment Registration Number: TBD

Date Summary Prepared: July 2, 2012

Device:
Trade Name: SpectraShield model 9500 Surgical Mask
Common /Classification Name: Surgical mask
Classification Product Code: ONT
Regulation Number: 21CFR 878.4040

Predicate Device Information: K090414 SpectraShield 9500 Surgical N95 Respirator

Device Description: The SpectraShield model 9500 Surgical Mask is a molded shape surgical mask composed of 4 layers of material, molded to form the mask. A 2-ply meltblown polypropylene middle layer is sandwiched by inner and outer layers of 100% polyester nonwoven fabric. The inner and outside layers of polyester nonwoven fabric include fibers that have been embedded with an antibacterial agent to provide antibacterial performance. The mask has 2 latex-free non-allergenic elastic straps and an aluminum nose strip.

Intended Use: The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, **tested for continuous use up to 8 hours,** embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the

surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions.

No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.

510(k) Summary
Device Comparison Table

	New Device	Predicate Device
510(k) #	To be determined	K090414
Company	NexEra Medical, Inc.	NexEra Medical, Inc.
Name/Model	**SpectraShield 9500 Surgical N95 Respirator *** (*with amended Intended use Statement)	**SpectraShield 9500 Surgical N95 Respirator**
Fabrics	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.
Nosepiece	100% Aluminum	100% Aluminum
Straps	(2) Polyamide fiber and elastic straps, latex free	(2) Polyamide fiber and elastic straps, latex free
Mask Style	Molded shape	Molded shape
Fluid Resistance ASTM F1862	Pass: Fluid Resistant @ 160mm Hg	Pass: Fluid Resistant @ 160mm Hg

NEXERA MEDICAL

	New Device	Predicate Device
	within safe orally ingestible levels.	within safe orally ingestible levels.
BioEfficacy :	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.40log_{10}reduction - 1 hour *H.influenzoe*: > 6.20log_{10}reduction - 1 hour MRSA: > 4.83log_{10}reduction - 1 hour	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.40log_{10}reduction - 1 hour *H.influenzoe*: > 6.20log_{10}reduction - 1 hour MRSA: > 4.83log_{10}reduction - 1 hour
BioEfficacy : after repeated exposures to perspiration over 12 hours	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.25log_{10}reduction - 1 hour *H.influenzoe*: > 4.18log_{10}reduction - 1 hour MRSA: > 4.11log_{10}reduction - 1 hour	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.25log_{10}reduction - 1 hour *H.influenzoe*: > 4.18log_{10}reduction - 1 hour MRSA: > 4.11log_{10}reduction - 1 hour
Intended Use Statement	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, **tested for continuous use up to 8 hours**, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator. The SpectraShield 9500 Surgical N95

NEXERA MEDICAL

	New Device	Predicate Device
	The SpectraShield 9500 Surgical N95 respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.	respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.

Conclusion: The subject device (SpectraShield model 9500 Surgical mask with the revised IFU referencing "tested for continuous use up to 8 hours"), and the predicate device (K090414) are the same device. The intention of this 510k submittal is to change the IFU to include the statement **"tested for continuous use up to 8 hours".**

The predicate device (K090414) was tested for bio-efficacy after repeated exposures to perspiration over a 12 hour period (see K090414 Repeat Challenge Protocol and Testing). The repeat challenge testing required the predicate device be repeatedly exposed to perspiration over a 12 hour period. Following the 12 hour exposure the predicate device was tested and demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. The intention of the repeated challenge and sustained exposure was to demonstrate that the device would still function as intended (99.99% kill) after wearing the device for 12 hours.

The IFU for the predicate device references "single use, disposable device". The proposed change to the IFU would read "single use, disposable device, tested for continuous use up to 8 hours."

It is our conclusion that the proposed change to the IFU does not change the intended use of the device, and we believe the change to the IFU further clarifies the intended use of the device. Additionally, we note the proposed change to the IFU demonstrate the device is as safe and as effective as the predicate device and performs equally as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G6
Silver Spring, MD 20993-0002

JUL 5 2012

Mr. Paul Sallarulo
Nexera Medical Incorporated
3343 West Commercial Boulevard Suite 103
Fort Lauderdale, Florida 33309

Re: K120244
Trade/Device Name: SpectraShield Model 9500 Surgical Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: ONT
Dated: June 21, 2012
Received: June 25, 2012

Dear Mr. Sallarulo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0: Indications for Use Statement

510(k) Number: 510(k) submission K12 0244

Device Name: SpectraShield model 9500 Surgical Respirator

Indications for Use:

The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable, surgical N95 respirator, tested for continuous use up to 8 hours, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: Streptococcus pyogenes, MRSA (Methicillin Resistant Staphylococcus aureus), and Haemophilus influenzae, under tested contact conditions.

No clinical studies have been conducted comparing the ability of an untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection, and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device, intended for occupational use to protect against microorganisms, body fluids, and particulate material.

Prescription Use _____ AND/OR Over –the-counter Use _X_
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120244

Sciessent

Acute Dermal, Sensitivity and Toxicity Summary

Acute Studies Comparison

AgION® Silver Antimicrobial	Type AD (72854-1)	Type AL	Zeomic Type AK Silver Zeolite A (EPA #71227-4)	Zeomic Type AJ Silver Zeolite A (EPA #71227-1)	Zeomic Type AC Silver Zeolite A (EPA #71227-7)
Silver	21.4%	10.0%	4.93%	2.5%	3.52%
Zinc	--	9.5%	12.90%	14.4%	--
Copper	--	--	--	--	6.1%
ACUTE ORAL TOXICITY - RAT					
LD50	>5000 mg/kg in females	Read across	>2000 mg/kg bw in males and females	>5000 mg/kg bw in males and females	>5000 mg/kg bw in males and females
MRID	469291-02	--	452521-02	446644-01	416158-02
ACUTE DERMAL TOXICITY - RABBIT					
LD50	>5000 mg/kg bw in males and females	Read across	>2000 mg/kg bw in males and females	>2000 mg/kg bw in males and females	>5000 mg/kg bw in males and females
MRID	469291-03	--	452521-03	446644-01	416158-03
ACUTE INHALATION TOXICITY - RAT					
LC50	>2.05 mg/L in males and females	Read across	>2.86 mg/L	--	>2.59 mg/L
MRID	469291-04	--	450243-02	416158-04 (Test Substance - Zeomic Type AC Silver Zeolite A)	416158-04
PRIMARY EYE IRRITATION - RABBIT					
Results	Mildly irritating	Read across	Category I ocular irritant	--	Moderate irritant
MRID	469291-05	--	450243-05	416385-01(Test Substance - Zeomic Type AC Silver Zeolite A)	416385-01
PRIMARY DERMAL IRRITATION - RABBIT					
Results	Non-irritating	Read across	Primary irritation index = 3.03	Primary irritation index = 0	Primary irritation index = 0.08
MRID	469261-06	--	450243-06	446644-02	416158-05
DERMAL SENSITIZATION - GUINEA PIG					
Results	Not a sensitizer	Read across	Not a sensitizer	Not a sensitizer	Not a sensitizer
MRID	469291-07	--	450243-03	416158-06 (Test Substance - Zeomic Type AC Silver Zeolite A)	416158-06

[redacted]-AJ10N
无机抗菌剂体外灭活 SARS 病毒试验总结

试验设计负责人：段淑敏

试验参加人员：段淑敏、赵新生、温瑞福、黄晶晶

试验日期：2003 年 9 月~2003 年 10 月

试验单位：中国疾病预防控制中心病毒病预防控制所

试验资料联系电话：010-63536459

委托单位：北京长城永毅科技发展有限公司

中国疾病预防控制中心病毒病预防控制所

2003 年 10 月 7 日

[redacted]-AJ10N 无机抗菌剂体外灭活 SARS 病毒试验总结

摘要：

在非洲绿猴肾传代细胞（VERO E6）培养内，采用病毒(CPE)法，检测[redacted]AJ10N 无机抗菌剂体外对 SARS 病毒的灭活效果，试验结果表明该材料在室温作用 6 小时以上对 SARS 病毒的有一定的灭活作用。

一、 试验目的

检测[redacted]AJ10N 无机抗菌剂在室温情况下与 SARS 病毒作用不同的时间，是否有灭活 SARS 病毒的作用，为加快灭活 SARS 病毒材料的筛选进度提供试验依据。

二、 试验材料

1．验证材料：

[redacted]-AJ10N 无机抗菌剂：呈白色粉末，每袋 10 克， 由北京长城永毅科技发展有限公司提供

2．阳性对照药物：

注射用更昔洛韦：批号 020802 由湖北科益药业股份有限公司提供。

3．病毒：

SARS-COV-P11 冠状病毒分离株（SARS 病人血清 11 号标本）由佑安医院提供，本室分离鉴定。

SARS-COV-P8 冠状病毒分离株 由病毒病预防控制所出血热室（李德新教授提供）

4．细胞：

非洲绿猴肾传代细胞（VERO E6），由本室提供。

5．Eagle's 细胞培养维持液等试验材料，均由本室提供。

三、实验方法

1. [redacted]-AJ10N 无机抗菌剂对 VERO E6 细胞的毒性测定

在 VERO E6 细胞培养内，采用细胞形态变化（CPE）法，用 Reed-Muench 法，计算药物半数中毒浓度（TD_{50}）和最大无毒浓度（TD_0）。

[redacted]-AJ10N 无机抗菌剂预处理：

将 6000μg/ml 的 [redacted]-AJ10N 无机抗菌剂放入一容器内，用 Eagle's 细胞维持液稀释后，放在磁力搅拌器上（温度为室温），在搅拌 2 小时、4 小时、6 小时的时候，分别取样进行稀释，即 6000μg/ml~187.5μg/ml，接种 VERO E6 细胞 96 孔培养板。

细胞形态变化 CPE 法：

VERO E6 细胞以 40 万/ml 浓度接种 96 孔培养板，37℃、5%CO_2 培养 24 小时，至细胞单层，分别加入预处理好的 [redacted]-AJ10N 无机抗菌剂，浓度为 6000μg/ml~187.5μg/ml，阳性对照药物倍比稀释为 6000μg/ml~187.5μg/ml，每浓度接种 4 孔，每孔 100μl。同时设正常细胞对照。置 37℃、5% CO_2 培养 5~7 天，每 24 小时在倒置显微镜下观察细胞形态变化，记录细胞形态变化（CPE）：以 25%以下变化为 +，26%~50%变化为 ++，51%~75%为 +++，76%~100%变化为 ++++，试验重复三次。

2. 在 VERO E6 细胞培养内对 SARS-COV-P11 分离鉴定

SARS-COV-P11（SARS 病人 11 号血清分离）：

VERO E6 细胞以每毫升 40 万浓度接种试管，37℃ 5%CO_2 培养 24 小时，弃掉培养液，每管加入 SARS 病人血清 0.2ml，37℃转鼓培养 5 小时后，加入维持液 1ml，同时设正常细胞对照，37℃转鼓培养 5~7 天。细胞出现 CPE 变化后，采用 PCR 的方法检测冠状病毒，11 号标本 PCR 阳性，确定为冠状病毒分离株。用终末稀释法纯化病毒 2 次，PCR 检测，SARS 病毒 S 基因测序仍为阳性，经免疫荧光测定双份 SARS 病人血清，IgM 阳性，IgG4 倍升高，确定为冠状病毒。采用病毒 CPE 法测定其效价。

在 VERO E6 细胞培养内对 SARS-COV-P1 和 SARS-COV-P8 毒株毒力的测定

病毒 CPE 法：

VERO E6 细胞以每毫升 40 万浓度接种 96 孔培养板，37℃ 5%CO_2 培养 24 小时，去掉培养液，分别将 2 株病毒稀释，稀释成 10^{-1} ~ 10^{-8}，8 个浓度，每浓度 4 孔，每孔 100μl，设正常细胞对照，37℃ 5%CO_2 培养 5~7 天，每 24 小时

在倒置显微镜下观察记录细胞形态变化（CPE）：以25%以下变化为“+”，26%~50%变化为“++”，51%~75%为“+++”，76%~100%变化为“++++”，用Reed-Muench法，计算病毒半数感染浓度$TCID_{50}$。

3. [redacted]-AJ10N无机抗菌剂在VERO E6细胞培养内对SARS-COV-P11和SARS-COV-P8的灭活作用

试验目的：

在VERO E6细胞培养内，采用病毒细胞（CPE）法，观察不同浓度的[redacted]-AJ10N无机抗菌剂对SARS病毒的灭活作用，计算半数有效浓度（IC_{50}）和最小有效浓度（MIC）及治疗指数TI，判断药效。

$100TCID_{50}$SARS病毒与[redacted]-AJ10N无机抗菌剂预处理：

将2株$100TCID_{50}$SARS病毒稀释液分别与750μg/ml的[redacted]-AJ10N无机抗菌剂放在一容器内，在磁力搅拌器上（温度为室温），搅拌2小时、4小时、6小时分别取样进行稀释，即750μg/ml~11.7μg/ml，接种VERO E6细胞96孔培养板。

病毒CPE法

VERO E6细胞以40万/ml浓度接种96孔培养板，37℃ 5% CO_2孵箱培养24小时，细胞培养至单层，弃掉培养液。加入经SARS病毒与[redacted]-AJ10N无机抗菌剂预处理的溶液，选用对细胞的最大无毒浓度（TD_0）2倍稀释7个浓度即为750μg/ml~11.7μg/ml，同时设预处理的[redacted]-AJ10N无机抗菌剂对照，2倍稀释7个浓度即750μg/ml ~ 5.9μg/ml，设阳性对照药物注射用更昔洛韦，药物选用对细胞的最大无毒浓度（TD_0）2倍稀释7个浓度即6000μg/ml ~ 5.9μg/ml，将稀释好的药物分别加入细胞孔内，每浓度4孔，同时设正常细胞对照和病毒对照，置37℃ 5% CO_2培养箱培养5~7天，逐日在倒置显微镜下观察病毒CPE，以病毒对照出现+++ — ++++时结束试验，用Reed - Muench法，计算药物的半数有效浓度（IC_{50}）和最小有效浓度（MIC）及治疗指数（TI）判断药效，试验重复三次。

四、试验结果

预备试验结果：

[redacted]-AJ10N无机抗菌剂对VERO E6细胞的毒性作用：

由北京长城永科技有限公司提供的[redacted]AJ10N无机抗菌剂和阳性对照药物注射用更昔洛韦在VERO E6细胞培养内，采用细胞形态变化（CPE）法。计算该材料的最大无毒浓度（TD_0）和半数中毒浓度（TD_{50}），以下试验结果为三次试验结果的均值。

1．[redacted]AJ10N无机抗菌剂对VERO E6细胞的毒性试验结果

验证材料：

[redacted]-AJ10N无机抗菌剂：最大无毒浓度（TD_0）为750±0μg/ml，半数中毒浓度（TD_{50}）为1500±0μg/ml

阳性对照药物：

注射用更昔洛韦：最大无毒浓度（TD_0）为>6000±0μg/ml，半数中毒浓度（TD_{50}）为>6000±0μg/ml 。

2．在VERO E6细胞培养内对SARS-COV-P11、SARS-COV-P8毒力测定结果

SARS-COV-P11：半数感染量（$TCID_{50}$）为 10^{-7}

SARS-COV-P8：半数感染量（$TCID_{50}$）为 10^{-7}

正式试验结果

1．[redacted]AJ10N无机抗菌剂与SARS-COV-P11分别作用2小时、4小时、6小时后，在VERO E6细胞培养内检测灭活的效果，分别以IC50、MIC、TI和灭活%为指标（以下试验数据为三次试验结果的均值）

检测灭活的效果（以IC50、MIC、TI为指标）

验证材料：

[redacted]-AJ10N无机抗菌剂：

室温作用2小时：病毒CPE法，半数有效浓度（IC_{50}）为188±0μg/ml，最小有效浓度（MIC）为94±0μg/ml ，治疗指数（TI）为8。

室温作用4小时：病毒CPE法，半数有效浓度（IC_{50}）为188±0μg/ml，最小有效浓度（MIC）为94±0μg/ml ，治疗指数（TI）为8。

室温作用6小时：病毒CPE法，半数有效浓度（IC_{50}）为94±0μg/ml，最小有效浓度（MIC）为46.8±0μg/ml ，治疗指数（TI）为16。

检测灭活的效果（以灭活%为指标）

室温作用2小时：病毒CPE法，当[redacted]-AJ10N无机抗菌剂稀释浓度>375μ

g/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 4 小时：病毒 CPE 法，当[redacted]-AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 6 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>188μg/ml 即可灭活 100%的 SARS 病毒，稀释为 94μg/ml 时可灭活 50%的 SARS 病毒，稀释为 46.8μg/ml 时可灭活 25%的 SARS 病毒。

阳性对照药物：

注射用更昔洛韦：CPE 法，药物半数有效浓度（IC_{50}）为 11.7±0μg/ml ，最小有效浓度（MIC）为 23.44±0μg/ml，治疗指数（TI）为 256。

2.[redacted]-AJ10N 无机抗菌剂与 SARS-COV- P8 作用 2 小时、4 小时、6 小时后，在 VERO E6 细胞培养内检测灭活的效果，分别以 IC50、MIC、TI 和灭活%为指标（以下试验数据为三次试验结果的均值）

检测灭活的效果（以 IC50、MIC、TI 为指标）

验证材料：

验证材料：

[redacted]-AJ10N 无机抗菌剂：

室温作用 2 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 4 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 188±0μg/ml，最小有效浓度（MIC）为 94±0μg/ml ，治疗指数（TI）为 8。

室温作用 6 小时：病毒 CPE 法，半数有效浓度（IC_{50}）为 94±0μg/ml，最小有效浓度（MIC）为 46.8±0μg/ml.，治疗指数（TI）为 16。

检测灭活的效果（以灭活%为指标）

室温作用 2 小时：病毒 CPE 法，当[redacted]AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 4 小时：病毒 CPE 法，当[redacted]-AJ10N 无机抗菌剂稀释浓度>375μg/ml 即可灭活 100%的 SARS 病毒，稀释为 188μg/ml 时可灭活 50%的 SARS 病

毒，稀释为 94μg/ml 时可灭活 25%的 SARS 病毒。

室温作用 6 小时：病毒 CPE 法，当 [redacted]AJ10N 无机抗菌剂稀释浓度>188μg/ml 即可灭活 100%的 SARS 病毒，稀释为 94μg/ml 时可灭活 50%的 SARS 病毒，稀释为 46.8μg/ml 时可灭活 25%的 SARS 病毒。

阳性对照药物：

注射用更昔洛韦：CPE 法，药物半数有效浓度（IC_{50}）为 11.7±0μg/ml，最小有效浓度（MIC）为 23.44±0μg/ml，治疗指数（TI）为 256。

总　　结

由北京长城永毅科技发展有限公司提供的 [redacted]AJ10N 无机抗菌剂和阳性对照药物注射用更昔洛韦在 VERO E6 细胞培养内，采用病毒 CPE 法，在 2 株 SARS 病毒分离株上进行验证，试验结果表明 [redacted]AJ10N 无机抗菌剂和 SARS 病毒在室温作用 6 小时以上，对 SARS 病毒有一定的灭活作用。

试验设计负责人：段淑敏

试验参加者：段淑敏、赵新生、温瑞福、黄晶晶

试验日期：2003 年 7 月~2003 年 10 月

试验单位：中国疾病预防控制中心病毒病预防控制所

疾控病毒资源中心

试验资料联系电话：010-63536459

委托单位：北京长城永毅科技发展有限公司

中国疾病预防控制中心病毒病预防控制所

2003 年 10 月 7 日

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ORIGINAL PAPER

Assessment of the Antiviral Properties of Zeolites Containing Metal Ions

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Abstract The antiviral properties of zeolite (sodium aluminosilicate) powders amended with metal ions were assessed using human coronavirus 229E, feline infectious peritonitis virus (FIPV), and feline calicivirus F-9. Zeolites containing silver and silver/copper caused significant reductions of coronavirus 229E after 1 h in suspension. The silver/copper combination yielded a >5.13-$\log_{10}$ reduction within 24 h. It was also the most effective (>3.18-$\log_{10}$) against FIPV after 4 h. Other formulations were ineffective against FIPV. On plastic coupons with incorporated silver/copper-zeolites, >1.7-$\log_{10}$ and >3.8-$\log_{10}$ reductions were achieved for coronavirus 229E and feline calicivirus within 24 h, respectively. Silver/copper zeolite reduced titers of all viruses tested, suggesting that it may be effective against related pathogens of interest [i.e., SARS coronavirus, other coronaviruses, human norovirus (calicivirus)]. Of note, it was effective against both enveloped and nonenveloped viruses. Metal-zeolites could therefore possibly be used in applications to reduce virus contamination of fomites and thus the spread of viral diseases.

Keywords Coronavirus · Calicivirus · Fomites · Antiviral · Copper · Silver

Introduction

By July of 2003, 8,098 probable cases of severe acute respiratory syndrome (SARS) resulting in 774 deaths had been reported to the World Health Organization (WHO) from 29 countries on five continents (Centers for Disease Control and Prevention 2003; World Health Organization 2004). A novel coronavirus, SARS coronavirus (SCoV) was isolated from patients (Ksiazek et al. 2003; Navas-Martín and Weiss 2004). Before the identification of SCoV, two coronaviruses were known to infect humans, strains 229E and OC43 (Navas-Martín and Weiss 2004). These cause mild, self-limiting, upper respiratory tract infections (Myint 1994) and belong to the Group I and Group II coronaviruses, respectively. SCoV possesses characteristics specific to all three coronavirus groups (Navas-Martín and Weiss 2004), but is not closely related to any (Poutanen et al. 2003). It is apparently an animal virus that recently adapted to cross the species barrier, allowing for human-to-human transmission (Antia et al. 2003).

Human norovirus (NoV) causes illness in an estimated 23 million people in the United States each year, resulting in 50,000 hospitalizations and 310 deaths (Mead et al. 1999). It has been suggested that NoV may be the leading cause of foodborne illness in the United States (Widdowson et al. 2005), responsible for approximately 66% of all cases with known etiologies (Mead et al. 1999) and at least 50% of all foodborne outbreaks of gastroenteritis (Centers for Disease Control and Prevention 2006). NoV was identified in 93% of nonbacterial gastroenteritis outbreaks by the Centers for Disease Control and Prevention (CDC) between 1997 and 2000 in the United States (Fankhauser et al. 2002). Similarly, surveillance by the Foodborne Viruses in Europe network found that NoV was responsible for greater than 85% of all nonbacterial gastroenteritis outbreaks from 1995 to 2000 (Lopman et al. 2003).

Nonenveloped viruses are typically more resistant to environmental conditions and the action of antimicrobials

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than enveloped viruses (Watanabe et al. 1989; Barker et al. 2001). Feline calicivirus has been found to persist for up to 28 days in a dry environment at room temperature (Doultree et al. 1999). Also, in a study by Smid et al. (1991), rabbit hemorrhagic disease virus (also a calicivirus) survived for at least 105 days in a dried state at room temperature. Viruses that cause symptoms such as vomiting or diarrhea are likely to contaminate the environment. In one study, 607 of 680 (89%) norovirus outbreaks were linked to person-to-person transmission (Evans et al. 1998) that included poor hand hygiene as well as surface-to-surface transmission (Barker et al. 2001). Also, successive outbreaks of norovirus infections in passengers on cruise ships on separate trips have strongly implicated environmental contamination (Barker et al. 2001). Enveloped viruses are typically less stable in the environment, yet the SCoV is able to survive on fomites for up to 96 h (Duan et al. 2003). The transmission of SCoV is believed to be multifactorial, with evidence from previous outbreaks suggestive of at least some role for contaminated fomites in the transmission of the virus (Dowell et al. 2004; Chu et al. 2005).

Zeolite (sodium aluminosilicate) powders (AgION Technologies, Wakefield, MA, USA) form porous crystals. Metal ions may reside within these pores and zeolites can act as ion exchangers, exchanging metal ions for other cations in the environment. Although the effect of metal-zeolites has been documented in numerous studies with bacteria (Bright et al. 2002; Takai et al. 2002; Cowan et al. 2003; Rusin et al. 2003; Kwakye-Awuah et al. 2008), the use of zeolite powders containing heavy metal ions to reduce coronaviruses and caliciviruses has not been previously reported. This paper describes the antiviral effect of suspensions of zeolite powders amended with silver (Ag), copper (Cu), and zinc (Zn) ions in phosphate-buffered saline against human coronavirus 229E and feline infectious peritonitis virus (FIPV; feline coronavirus). This report also includes tests of the survival of human coronavirus 229E, FIPV, and feline calicivirus on the surfaces of plastics with zeolite containing Ag and Cu ions incorporated into the plastic.

Human coronavirus 229E and FIPV were employed in this study as surrogates for other coronaviruses. Feline calicivirus was also included as a surrogate for NoV. There is currently no practical method for propagating human NoV in cell culture monolayers. Feline calicivirus, on the other hand, grows readily in cell culture. It is in the same family as human NoV and is commonly used as a NoV surrogate in experiments (Slomka and Appleton 1998; Clay et al. 2006) because of its biochemical and genetic similarities to NoV (Jiang et al. 1993).

Materials and Methods

Virus Preparation

Human coronavirus strain 229E (ATCC #VR-740) was obtained from the American Type Culture Collection (ATCC, Manassas, VA, USA). It was maintained on MRC-5 (fetal human lung fibroblast, ATCC #CCL-171) cell line monolayers with minimal essential medium (MEM, modified with Earle's salts, Irvine Scientific, Santa Ana, CA, USA) containing 2% fetal bovine serum (FBS, Hyclone, Logan, UT, USA) at an incubation temperature of 35°C with 5% CO_2. Coronavirus 229E replicates better at this temperature than at 37°C. Feline infectious peritonitis virus (FIPV; ATCC #VR-990) and feline calicivirus strain F-9 (ATCC #VR-782) were maintained in the same manner on CRFK (Crandell Reese feline kidney, ATCC #CCL-94) cell line monolayers.

Viruses were purified by centrifugation ($750\times g$) to remove cell debris followed by polyethylene glycol (9% PEG, 0.5 mol/l NaCl) precipitation. Viral titrations were performed using the Reed-Muench method (Payment and Trudel 1993) to determine the tissue culture infectious dose that affected 50% of the cultures ($TCID_{50}$).

Metal-Zeolite Powders in Suspension

Coronavirus strains 229E and FIPV were added to Erlenmeyer flasks containing 30.0 ml of phosphate buffered saline (PBS, pH 7.4; Sigma-Aldrich, St. Louis, MO, USA) with 10.0 mg of suspended zeolite test powder [either unamended powder, 20.0% Ag (w/w), 3.5% Ag/6.5% Cu, or 0.6% Ag/14% Zn/80% ZnO] (AgION Technologies, Wakefield, MA, USA). Positive control flasks without zeolite powder were also included. All experiments were performed in duplicate.

The positive control flasks (without zeolite powders) were sampled immediately ($t = 0$ h) by removing 1.0 ml from each flask and placing it into 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA). The 2.0 ml volumes were mixed thoroughly and placed into 4.0 ml of PBS (pH 7.4). All test flasks were then placed on an orbital shaker (200 rpm) at room temperature (23°C) and were sampled at 1, 4, and 24 h in the manner described previously. All samples were frozen in 1.0 ml aliquots at −80°C. Frozen aliquots were subsequently assayed using the Reed-Muench $TCID_{50}$ method as before (Payment and Trudel 1993).

Plastics with Incorporated Metal-Zeolites

Plastic coupons (5 cm by 5 cm) with either 5 or 10% (w/w) zeolite (containing 3.5% Ag and 6.5% Cu ions) incorporated

into the plastic during manufacture prior to molding were used in this set of experiments. To further clarify, the test coupons all contained zeolites amended with 3.5% Ag and 6.5% Cu (w/w), but with differing amounts [5 or 10% w/w] of this Ag/Cu zeolite incorporated into the plastic. The plastic coupons were sanitized with 70% ethanol, allowed to air dry, and then evenly inoculated using a sterile glass rod with 0.1 ml of diluted virus (human coronavirus 229E or feline calicivirus). Three control coupons (without zeolite) were sampled immediately using a sterile polyester swab dipped in 1.0 ml of D/E neutralizing broth (Remel, Lenexa, KS, USA) to determine the original virus titer recovered. The remaining coupons were then placed in humidity chambers at a relative humidity of approximately 95% and incubated at room temperature (23°C). At 1, 4, and 24 h, the coupons were swabbed as before. Because the experiment was conducted in a nonsterile environment, samples were filtered using a 0.22-μm pore size Acrodisc® syringe filter (Pall, Ann Arbor, MI, USA) pre-wetted with 3% beef (pH 7.0) extract to remove any contaminating bacteria/fungi and then frozen in 1.0 ml aliquots at −80°C. All experiments were performed in triplicate. Frozen aliquots were subsequently enumerated in duplicate using a plaque-forming assay (for feline calicivirus) described by Bidawid et al. (2003) or the Reed-Muench $TCID_{50}$ method (for coronavirus 229E) as described previously (Payment and Trudel 1993).

Statistical Analysis

A Student's *t* test was used to compare the viral counts recovered from the flasks containing test powder suspensions and test plastic coupons to those recovered from the positive controls.

Results

Metal-Zeolite Powders in Suspension

Amended zeolite powder suspensions were compared to determine which heavy metal combinations demonstrated the greatest activity against human coronavirus 229E. Unamended powder was used as a control to evaluate the effect of adsorption. The effect of Cu alone was undetermined. The results of the suspension tests are presented in Table 1. The results from the flasks containing zeolite control powder indicate that removal of virus was not due to adsorption by zeolite particles. Of the powder suspensions tested, the 3.5% Ag/6.5% Cu ion combination was the most efficacious, yielding a 1.08-$\log_{10}$ reduction of 229E after 1 h, a 2.06-$\log_{10}$ reduction after 4 h, and a >5.13-$\log_{10}$ reduction after 24 h of exposure. The greatest reductions observed for the other amended powders were following 24 h of exposure; nevertheless, the reductions at 24 h were not significantly greater ($P = 0.274$) than those after 4 h of exposure.

The 3.5% Ag/6.5% Cu combination was also effective (>3.18-$\log_{10}$ reduction) against FIPV within 4 h; however, neither of the other formulations was effective against FIPV, even after 24 h of exposure.

Plastics with Incorporated Metal-Zeolites

The results for the virus survival on the plastics with incorporated Ag/Cu-zeolite are shown in Table 2. Significant reductions were observed for coronavirus 229E on the Ag/Cu-zeolite plastic coupons after 24 h of exposure with a 1.84-$\log_{10}$ and a 1.77-$\log_{10}$ reduction achieved on the 5% and 10% (wt/wt) zeolite coupons, respectively. The

Table 1 $\log_{10}$ reduction of coronaviruses after exposure to zeolite test powders amended with heavy metals

Virus	Time (h)	Positive control[a]	Zeolite control[b]	Amended zeolite powder (w/w)		
				3.5% Ag 6.5% Cu	20% Ag	0.6% Ag 14% Zn 80% ZnO
229E (human)	1	0.00 ± 0.00	0.00 ± 0.24	1.08* ± 0.07	0.43* ± 0.09	0.50 ± 0.24
	4	0.70 ± 0.00	0.26 ± 0.28	2.06* ± 0.18	1.28* ± 0.12	1.30 ± 0.00
	24	0.59 ± 0.14	0.16 ± 0.05	>5.13* ± 0.00[c]	1.92* ± 0.47	1.45 ± 0.66
FIPV (feline)	1	0.16 ± 0.12	0.08 ± 0.13	1.91* ± 0.31	0.14 ± 0.61	0.50 ± 0.66
	4	0.01 ± 0.20	0.08 ± 0.20	>3.18* ± 0.00[c]	0.40 ± 0.69	0.42 ± 0.48
	24	0.10 ± 0.36	0.35 ± 0.43	>3.18* ± 0.00[c]	0.30 ± 1.52	0.53 ± 1.06

The experiments were conducted in duplicate at room temperature. The original titer was 5.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.6×10^3 $TCID_{50}$/ml for feline coronavirus. The ± indicates the standard deviation for the duplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Virus, phosphate buffered saline (PBS) and D/E neutralizer

[b] Virus, phosphate buffered saline (PBS), unamended zeolite powder, and D/E neutralizer

[c] Below the detection limit

Table 2 Log_{10} reduction of viruses on plastic coupons impregnated (5% or 10%) with zeolite powder (containing 6.5% copper, 3.5% silver ions)

Virus	Time (h)	Positive control[a]	5% Zeolite (w/w)	10% Zeolite (w/w)
Coronavirus 229E	1	0.22 ± 0.51	0.93 ± 0.05	0.80 ± 0.00
	4	0.50 ± 0.61	0.52 ± 0.47	0.44 ± 0.24
	24	0.67 ± 0.61	1.84* ± 0.20	1.77* ± 0.24
Feline calicivirus	1	0.04 ± 0.03	0.25* ± 0.06	0.67* ± 0.14
	4	0.17 ± 0.08	0.64* ± 0.19	0.96 ± 1.45
	24	0.40 ± 0.32	3.84 ± 1.02	5.05* ± 0.21

The experiment was conducted in triplicate at room temperature. The original titer was 4.0×10^5 $TCID_{50}$/ml for human coronavirus and 5.0×10^6 PFU/ml for feline calicivirus. The ± indicates the standard deviation for the triplicate samples

* Reduction was statistically significant ($P \leq 0.05$) in comparison to the positive control

[a] Plastic coupons without zeolite

reductions for feline calicivirus were greater, including a 3.84-log_{10} reduction on the 5% Ag/Cu-zeolite coupons and a 5.05-log_{10} reduction on the 10% Ag/Cu-zeolite coupons after 24 h.

Discussion

To date, there have been no detailed studies of the interaction between heavy metals and viruses. Viruses that contain sulfhydryl termini may bind silver, interfering with viral replication (Davies and Etris 1997). Silver may also modify the adsorption of viruses to host cells (Tzagoloff and Pratt 1964). Thurman and Gerba (1989) suggested that viral inactivation might not require a metabolic process. For instance, the virus may be immobilized to a surface, the host-cell receptors may be blocked, or the nucleic acid within the viral capsid may be inactivated.

Copper is toxic to most microorganisms at higher concentrations, possibly due to the blocking of functional groups on proteins and the inactivation of enzymes (Faundez et al. 2004). Zinc oxide produces an active oxygen species at its surface that has a similar oxidative effect to hydrogen peroxide when it dissociates. This may damage the viral capsid and allow more metal ions inside the virus.

Unlike the respiratory disease caused by coronavirus 229E, FIPV causes gastrointestinal symptoms. The fact that Ag/Cu zeolite is effective against two substantially different coronaviruses suggests that it may also be effective in reducing the SCoV which causes severe respiratory disease, but which may also have a gastrointestinal component and is shed in the feces for greater than 10 weeks (Leung et al. 2003). The Ag/Cu zeolite was also effective against the nonenveloped feline calicivirus whose physical properties differ greatly from the enveloped coronaviruses.

Zeolite powders containing antiviral heavy metals have many potential applications. They may be added to materials such as plastics, paints, and synthetic fabrics (Quintavalla and Vicini 2002; Takai et al. 2002), and may be bonded to surfaces such as stainless steel (Bright et al. 2002; Cowan et al. 2003; Rusin et al. 2003). The effectiveness of the Ag/Cu zeolite against substantially different viruses appears promising for its potential use in applications to reduce environmental contamination of fomites by viral pathogens and thus the spread of diseases. Additional tests utilizing zeolites containing copper ions alone or in combination with various metals against other disparate viruses are needed.

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References

Antia, R., Rogoes, R. R., Koella, J. C., & Bergstrom, C. T. (2003). The role of evolution in the emergence of infectious diseases. *Nature, 426*, 658–661.

Barker, J., Stevens, D., & Bloomfield, S. F. (2001). Spread and prevention of some common viral infections in community facilities and domestic homes. *Journal of Applied Microbiology, 91*, 7–21.

Bidawid, S., Malik, N., Adegunrin, O., Sattar, S. S., & Farber, J. M. (2003). A feline kidney cell line-based plaque assay for feline calicivirus, a surrogate for Norwalk virus. *Journal of Virological Methods, 107*, 163–167.

Bright, K. R., Gerba, C. P., & Rusin, P. A. (2002). Rapid reduction of *Staphylococcus aureus* populations on stainless steel surfaces by zeolite ceramic coatings containing silver and zinc ions. *The Journal of Hospital Infection, 52*, 307–309.

Centers for Disease Control and Prevention. (2003). Revised U.S. surveillance case definition for severe acute respiratory syndrome (SARS) and update on SARS cases–United States and Worldwide, December 2003. *Morbidity and Mortality Weekly Report, 52*, 1202–1206.

Centers for Disease Control and Prevention. (2006). Norovirus: Technical fact sheet. http://www.cdc.gov/ncidod/dvrd/revb/gastro/downloads/noro-factsheet.pdf. Accessed 22 September 2008.

Chu, C. M., Cheng, V. C. C., Hung, I. F. N., Chan, K. S., Tang, B. S. F., Tsang, T. H. F., et al. (2005). Viral load distribution in SARS outbreak. *Emerging Infectious Diseases, 11*, 1882–1886.

Clay, S., Maherchandani, S., Malik, Y. S., & Goyal, S. M. (2006). Survival on uncommon fomites of feline calicivirus, a surrogate of noroviruses. *American Journal of Infection Control, 34*, 41–43.

Cowan, M. M., Abshire, K. Z., Houk, S. L., & Evans, S. M. (2003). Antimicrobial efficacy of a silver-zeolite matrix coating on stainless steel. *Journal of Industrial Microbiology & Biotechnology, 30*, 102–106.

Davies, R. I., & Etris, S. F. (1997). Development and functions of silver in water-purification and disease-control. *Catalysis Today, 36*, 107–114.

Doultree, J. C., Druce, J. D., Birch, C. J., Bowden, D. S., & Marshall, J. A. (1999). Inactivation of feline calicivirus, a Norwalk virus surrogate. *The Journal of Hospital Infection, 41*, 51–57.

Dowell, S. F., Simmerman, J. M., Erdman, D. D., Wu, J. S. J., Chaovavanich, A., Javadi, M., et al. (2004). Severe acute respiratory syndrome coronavirus on hospital surfaces. *Clinical Infectious Diseases, 39*, 652–657.

Duan, S. M., Zhao, X. S., Wen, R. F., Huang, J. J., Pi, G. H., Zhang, S. X., et al. (2003). Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation. *Biomedical and Environmental Sciences, 16*, 246–255.

Evans, H. S., Madden, P., Douglas, C., Adak, G. K., O'Brien, S. J., Djuretic, J., et al. (1998). General outbreaks of infectious intestinal disease in England and Wales: 1995 and 1996. *Communicable Disease and Public Health, 1*, 165–171.

Fankhauser, R. L., Monroe, S. S., Noel, J. S., Ando, T. A., & Glass, R. I. (2002). Epidemiologic and molecular trends of Norwalk-like viruses associated with outbreaks of gastroenteritis in the United States. *The Journal of Infectious Diseases, 186*, 1–7.

Faundez, G., Troncoso, M., Navarrete, P., & Figueroa, G. (2004). Antimicrobial activity of copper surfaces against suspensions of *Salmonella enterica* and *Campylobacter jejuni*. *BMC Microbiology, 4*, 19.

Jiang, X., Wang, M., Wang, K., & Estes, M. K. (1993). Sequence and genomic organization of Norwalk virus. *Virology, 195*, 51–61.

Ksiazek, T. G., Erdman, D., Goldsmith, C. S., Zaki, S. R., Peret, T., Emery, S., et al. (2003). A novel coronavirus associated with severe acute respiratory syndrome. *The New England Journal of Medicine, 348*, 1953–1966.

Kwakye-Awuah, B., Williams, C., Kenward, M. A., & Radecka, I. (2008). Antimicrobial action and efficiency of silver-loaded zeolite X. *Journal of Applied Microbiology, 104*, 1516–1524.

Leung, W. K., To, K. F., Chan, P. K., Chan, H. L., Wu, A. K., Lee, N., et al. (2003). Enteric involvement of severe acute respiratory syndrome-associated coronavirus infection. *Gastroenterology, 125*, 1011–1017.

Lopman, B. A., Reacher, M. H., van Duijnhoven, Y., Hanon, F. X., Brown, D., & Koopmans, M. (2003). Viral gastroenteritis outbreaks in Europe, 1995–2000. *Emerging Infectious Diseases, 9*, 90–96.

Mead, P. S., Slutsker, L., Dietz, V., McCaig, L. F., Bresee, J. S., Shapiro, C., et al. (1999). Food-related illness and death in the United States. *Emerging Infectious Diseases, 5*, 607–665.

Myint, S. H. (1994). Human coronaviruses—A brief review. *Reviews in Medical Virology, 4*, 35–46.

Navas-Martín, S., & Weiss, S. (2004). Coronavirus replication and pathogenesis: Implications for the recent outbreak of severe acute respiratory syndrome (SARS), and the challenge for vaccine development. *Journal of Neurovirology, 10*, 75–85.

Payment, P., & Trudel, M. (1993). Isolation and identification of viruses. In P. Payment & M. Trudel (Eds.), *Methods and techniques in virology* (pp. 32–33). New York: Marcel Dekker.

Poutanen, S. M., Low, D. E., Henry, B., Finkelstein, S., Rose, D., Green, K., et al. (2003). Identification of severe acute respiratory syndrome in Canada. *The New England Journal of Medicine, 348*, 1995–2005.

Quintavalla, S., & Vicini, L. (2002). Antimicrobial food packaging in meat industry. *Meat Science, 62*, 373–380.

Rusin, P., Bright, K., & Gerba, C. (2003). Rapid reduction of *Legionella pneumophila* on stainless steel with zeolite coatings containing silver and zinc ions. *Letters in Applied Microbiology, 36*, 69–72.

Slomka, M. J., & Appleton, H. (1998). Feline calicivirus as a model system for heat inactivation studies of small round structured viruses in shellfish. *Epidemiology and Infection, 121*, 401–407.

Smid, B., Valicek, L., Rodak, L., Stepanek, J., & Jurak, E. (1991). Rabbit haemorrhagic disease: An investigation of some properties of the virus and evaluation of an inactivated vaccine. *Veterinary Microbiology, 26*, 77–85.

Takai, K. T., Ohtsuka, T., Senda, Y., Nakao, M., Yamamoto, K., Matsuoka-Junji, J., et al. (2002). Antibacterial properties of antimicrobial-finished textile products. *Microbiology and Immunology, 46*, 75–81.

Thurman, R. B., & Gerba, C. P. (1989). The molecular mechanisms of copper and silver ion disinfection of bacteria and viruses. *CRC Critical Reviews in Environmental Control, 18*, 295–315.

Tzagoloff, H., & Pratt, D. (1964). The initial steps in infection with coliphage M13. *Virology, 24*, 372–380.

Watanabe, Y., Miyata, H., & Sato, H. (1989). Inactivation of laboratory animal RNA-viruses by physicochemical treatment. *Jikken Dobutsu, 38*, 305–311.

Widdowson, M. A., Sulka, A., Bulens, S. N., Beard, R. S., Chaves, S. S., Hammond, R., et al. (2005). Norovirus and foodborne disease, United States, 1991–2000. *Emerging Infectious Diseases, 11*, 95–102.

World Health Organization. (2004). *WHO guidelines for the global surveillance of severe acute respiratory syndrome (SARS) Updated recommendations October 2004*. New Delhi, India: Department of Communicable Disease Surveillance and Response, Regional Office for South-East Asia, World Health Organization.

HeiQ Viroblock

Viroblock data portfolio (Viroblock SA) – 2013/15

March 2020

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Outline

1. Background
2. Test methods
3. Summary of studies
4. Selected examples

1. Background

Testing portfolio:

- Antiviral testing was commissioned by Swiss company Viroblock SA over period 2013 – 2015 and transitioned to Swiss company HeiQ Materials AG in 2020.
- Testing was performed by:
  - Microbiotest (A division of Microbac Laboratories), 105-B Carpenter Drive, Sterling VA 20164, USA
- Test materials were supplied by Viroblock SA
  - Test articles included face masks and textile samples
  - Samples with Viroblock non-phospholipid vesicle treatment were compared against untreated control samples and conventional market available articles

HeiQ & Viroblock SA:

- HeiQ Materials implemented the Viroblock SA vesicle treatment technology [1] in 2014 and then during period Feb-March 2020 including final purchase of the Viroblock test data portfolio and trademarks
- HeiQ augmented the Viroblock vesicle technology with EPA registerd silver-based components to provide broader robustness of antimicrobial and antiviral effect to the treatment formulation

[1] Pelet, T. and Wallach, D.F., VIROBLOCK SA, 2014. Composition for inactivating an enveloped virus. U.S. Patent 8,889,398.

2. Test methods

Test methods

- The following test methods were used in the testing battery:

#	Test	Method basis	Description	Article forms	Virus strains
1	Aerosol challenge test	ASTM F2101	a	Face masks	Various
2	Misting spray contact test	AATCC 100	b	Textiles & face mask fabrics	Various

a. **Aerosol challenge test:** This test is designed to evaluate virus filtration efficiency of treated face mask materials against viruses using a two-chamber system and aerosolized virus. This test is based on the ASTM Method F 2101.01 entitled "Standard test methods for evaluating the bacterial filtration efficiency of treated face mask materials, using a biological aerosol of *Staphylococcus aureus*", with modifications and customization to virus testing.

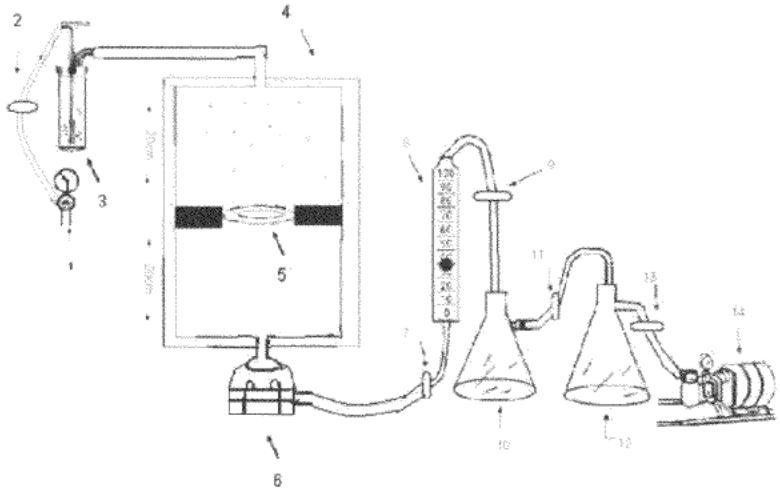
b. **Misting spray contact test:** This test is designed to evaluate virucidal effectiveness of the treated fabric or mask material via direct contact with the test virus. It determines the potential of the test fabric or face mask, which is impregnated with antimicrobial agents, to inactivate virus on direct contact. The test is designed to simulate consumer use and is based on AATCC Test Method 100 with customization for virus testing.

[1] ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus, American Society for Testing Materials
[2] AATCC Test Method 100, Antibacterial Finishes on Textile Materials: Assessment of', American Association of Textile Chemists and Colorists, AATCC Technical Manual (2019).

Aerosol challenge tests

Method summary

- Based on ASTM Method F 2101.01 with modifications and customization to virus testing.
- Test mask mounted and sealed within a test chamber
- A nebulizer delivers an aerosol of the target virus inoculum to the upstream side of the mask
- A vacuum draws air through the mask
- A collection dish placed below the mask downstream collects aerosol droplets that pass through the mask sample
- The reduction in infectivity with and without mask is calculated as an indicator of effectiveness



Key

1. High pressure air source
2. Filter #1
3. Nebulizer
4. Mask chamber
5. Test material location
6. Anderson Impactor
7. Filter #2
8. Calibrated Flowmeter, L/min
9. Filter #3
10. 4L Vacuum flask #1
11. Filter #4
12. 4L Vaccum flask #2
13. Filter #5
14. Vacuum pump

Misting study

Method summary

- Based on AATCC Test Method 100 with customization for virus testing
- Spray mist of the target virus inoculum applied evenly onto the surface of the fabric (2 x 2 in. area) from a distance of 3 to 6 in.
- Let sample stand for the contact time of interest
- Recover residues into a recovery medium (stomacher)
- Evaluate residual infectivity of recovered residues
- The reduction in infectivity compared to the starting inoculum is calculated as an indicator of effectiveness

3. Summary of studies

Studies: Aerosol challenge test

Study ID	Study title	Report date	Test method	Articles	Agent	Test articles	Reduction	95% CI
798-108	Evaluation of virus filtration efficiency of treated face masks against aerosolized influenza A virus	20/03/2013	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	VB-FFP2	**4.33**	0.27
						VB-FFP2-Control	**2.73**	0.16
						VB-SM	**3.90**	0.16
						VB-SM-Control	**1.34**	0.28
798-110	Evaluation of virus filtration efficiency of treated face masks against aerosolized influenza A virus	29/05/2013	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	FFP2	**5.38**	0.43
						FFP2 CTL	**3.63**	0.43
						FFP3	**3.73**	0.28
						FFP3 CTL	**1.73**	0.28
798-111	Evaluation of filtration efficiency of treated face masks against aerosolized virus avian influenza A virus (H5N1)	4/06/2013	Aerosol challenge test	Face mask	H5N1 (Avian Influenza A)	FFP2	**4.86**	0.16
						FFP2 CTL	**2.86**	0.16
798-112	Evaluation of filtration efficiency of treated face masks against aerosolized virus Human Coronavirus	13/06/2013	Aerosol challenge test	Face mask	229E (Human Coronavirus)	FFP2	**4.48**	0.16
						FFP2 CTL	**2.90**	0.16
798-114	Evaluation of filtration efficiency of treated face masks against aerosolized virus - 2013 Influenza A (H7N9) virus	19/07/2013	Aerosol challenge test	Face mask	H7N9 (2013 Influenza A virus)	FFP2	**4.24**	0.16
						FFP2 CTL	**1.93**	0.28
798-115	Evaluation of filtration efficiency of treated face masks against aerosolized virus - Respiratory Syncytial Virus	28/08/2013	Aerosol challenge test	Face mask	RSV (Respiratory Syncytial Virus)	FFP2	**3.10**	0.08
						FFP2 CTL	**1.40**	0.14
798-116	Evaluation of filtration efficiency of treated face masks against aerosolized mycobacterium Mycobacterium terrae	29/11/2013	Aerosol challenge test	Face mask	Mycobacterium terrae (ATCC 15755)	FFP2	**1.98**	0.00
						FFP2 CTL	**0.26**	0.01
798-117	Evaluation of virus filtration efficiency of treated face masks against aerosolized virus - influenza A virus (H1N1)	25/03/2014	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	Facemate classic (VB)	**4.19**	0.02
						Facemate classic (C)	**2.39**	0.43
798-120	Evaluation of virus filtration efficiency of treated face masks against aerosolized virus - influenza A virus (H1N1)	31/07/2014	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	Vflex 9105	**2.15**	0.25
						PFRP2-62408	**1.95**	0.14
						FFP2 NR-VR202	**2.30**	0.38
						FFP2D NR-VBHF002	**3.55**	0.38
						Control mask	**1.90**	0.25
798-121	Evaluation of virus filtration efficiency of treated face masks against aerosolized virus - influenza A virus (H1N1)	26/11/2014	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	FFP2 NRD-VBHF002 (old version)	**5.22**	0.00
						FFP2 NRD-VBHF002 (new version)	**5.22**	0.00
						FFP3 NRD 3M (reference mask)	**5.11**	0.11
798-122	Evaluation of virus filtration efficiency of treated face masks against aerosolized virus - influenza A virus (H1N1)	18/02/2015	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	VBHF002P	**4.47**	0.27
						VBHF002S	**4.96**	0.30
798-125	Evaluation of virus filtration efficiency of treated face masks against aerosolized virus - influenza A virus (H1N1)	17/07/2015	Aerosol challenge test	Face mask	H1N1 (Human Influenza A)	Viroblock 3P FFP3 Mask	**3.57**	0.29
						Valmy FFP3 Mask	**2.54**	0.46

Studies: Misting test

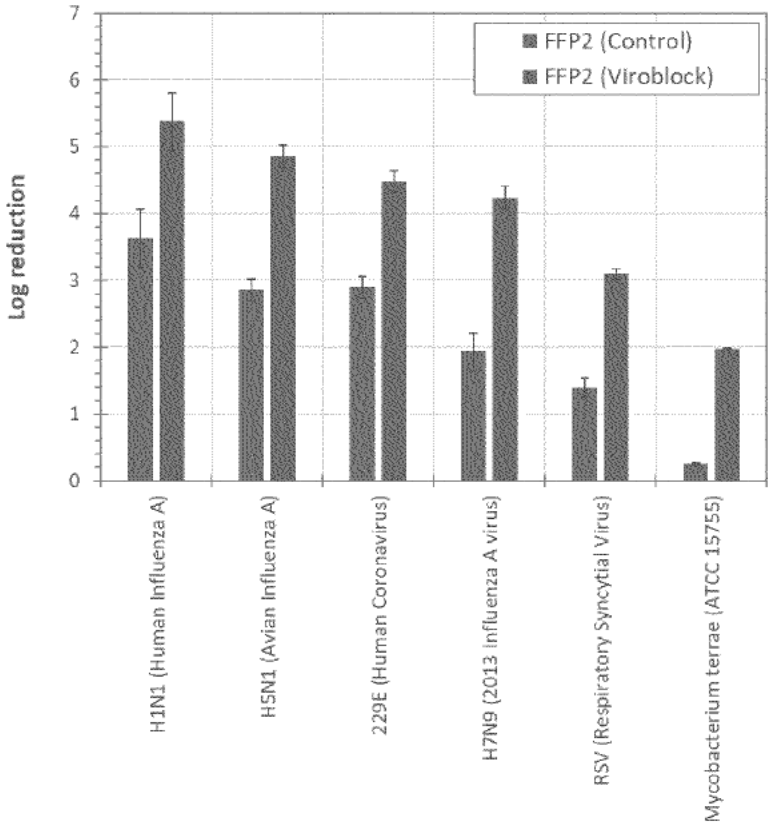
Study ID	Short title	Report date	Test method	Articles	Agent	Test articles	Time (mins.)	Reduction	95% CI
798-118	Assessment of virucidal effectiveness of treated fabric material using Influenza A virus (H1N1) misting study	27/03/2014	Misting spray test	Cotton fabric	H1N1 (Human Influenza A)	Cotton fabric (T)	10	**1.59**	0.33
							30	**1.89**	0.16
							60	**3.12**	0.31
						Cotton fabric (C)	10	**2.04**	0.33
							30	**2.31**	0.13
							60	**2.16**	0.00
798-119	Assessment of virucidal effectiveness of treated fabric material using Influenza A virus (H1N1) misting study	29/04/2014	Misting spray test	Cotton fabric	H1N1 (Human Influenza A)	Cotton fabric (T)	60	**3.35**	0.00
							120	**2.47**	0.00
							180	**2.47**	0.00
						Cotton fabric (C)	60	**0.63**	0.43
							120	**0.15**	0.16
							180	**0.40**	0.16
798-123	Assessment of virucidal effectiveness of treated fabric via direct contact Influenza A Virus (H1N1) misting study	29/04/2015	Misting spray test	Cotton fabric	H1N1 (Human Influenza A)	White Cotton #1	10	**2.13**	0.98
							30	**2.04**	0.24
							60	**1.79**	0.25
						White Cotton #2	10	**2.21**	0.49
							30	**2.64**	0.00
							60	**2.64**	0.00
						White Cotton #3	10	**1.89**	0.00
							30	**2.79**	0.25
							60	**2.54**	0.24
						White Cotton #4	10	**2.29**	0.25
							30	**3.14**	0.00
							60	**3.04**	0.24
						White Cotton #5	10	**3.39**	0.00
							30	**3.77**	0.29
							60	**3.39**	0.00
798-124	Assessment of bactericidal effectiveness of treated fabric via direct contact Staphylococcus aureus misting study	9/07/2015	Misting spray test	Cotton fabric	Staphylococcus aureus (ATCC 6538)	White Cotton #1	30	**1.07**	
							60	**1.26**	
							120	**1.22**	
						White Cotton #4	30	**1.07**	
							60	**1.26**	
							120	**1.22**	
						White Cotton #5	30	**-0.08**	
							60	**0.53**	
							120	**0.38**	
798-126	Assessment of virucidal effectiveness of treated fabric via direct contact Influenza A Virus (H1N1) misting study	24/11/2015	Misting spray test	Respirators	H1N1 (Human Influenza A)	FFP2 Respirator (Lot 31001)		**4.18**	
						FFP2 Respirator (Lot 31005)		**3.61**	
						FFP2 Respirator (Lot 31009)		**3.43**	
						FFP2 Respirator (Lot 31016)		**3.61**	
						FFP2 Respirator (Control fabric)		**1.11**	

4. Selected examples

Aerosol challenge

- FFP2 face masks (Untreated control vs Viroblock treated)

		Log reduction		% reduction	
Study ID	Agent	Control	Viroblock	Control	Viroblock
798-110	H1N1 (Human Influenza A)	**3.63**	**5.38**	99.9766%	99.9996%
798-111	H5N1 (Avian Influenza A)	**2.86**	**4.86**	99.862%	99.999%
798-112	229E (Human Coronavirus)	**2.90**	**4.48**	99.874%	99.997%
798-114	H7N9 (2013 Influenza A virus)	**1.93**	**4.24**	98.825%	99.994%
798-115	RSV (Respiratory Syncytial Virus)	**1.40**	**3.10**	96.02%	99.92%
798-116	Mycobacterium terrae (ATCC 15755)	**0.26**	**1.98**	45.05%	98.95%



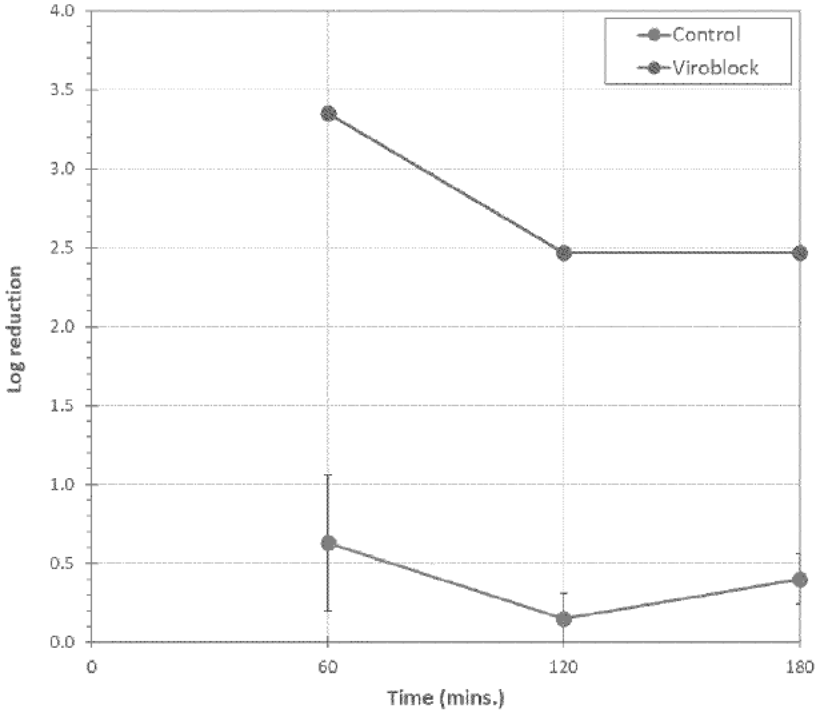
- **Viroblock treated FFP2 mask shows dramatically improved antiviral effect**
- **Effective against key virus types: H1N1, H5N1, H7N9, Coronavirus (229E), and RSV**

FDAFOIA-OC- 2020-5361-00348

Misting study

- Cotton fabric (Untreated control vs Viroblock treated)
- Exposure to Human influenza A (H1N1)

Study	Agent	Time (mins)	**Control**	**Viroblock**
798-119	H1N1 (Human Influenza A)	60	**0.63**	**3.35**
		120	**0.15**	**2.47**
		180	**0.40**	**2.47**



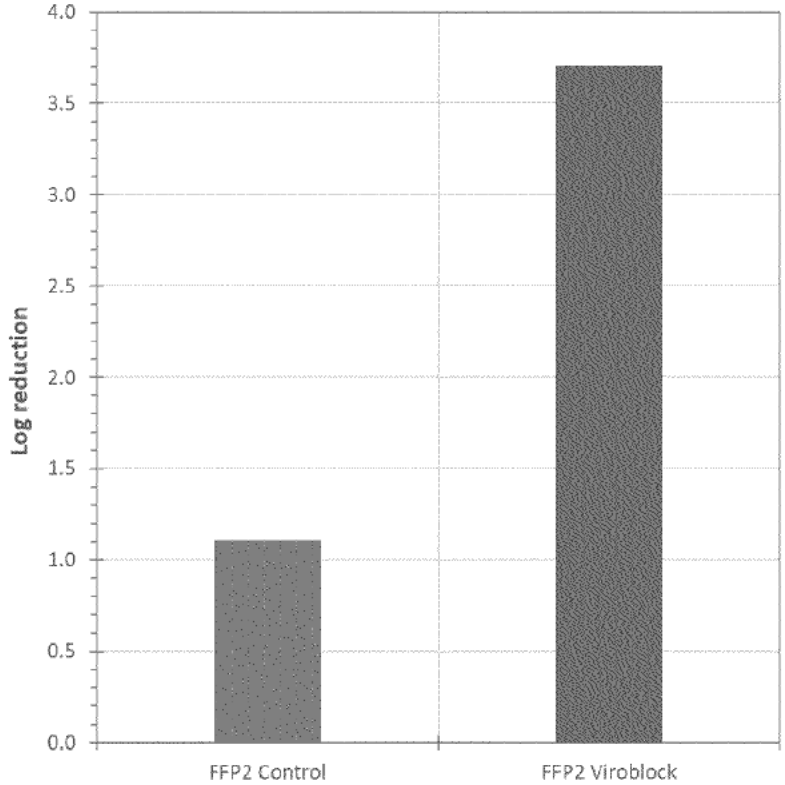
- **Viroblock treated fabric shows dramatically improved reduction in virus infectivity over a 3 hour period**

Misting study

- FFP2 face masks (Untreated control vs Viroblock treated)

Study	Agent	FFP2 Control	**FFP2 Viroblock**
798-126	H1N1 (Human Influenza A)	1.11	**3.71**

- **Viroblock treated FFP2 mask shows dramatically improved reduction in virus infectivity (mist contact)**



FDAFOIA-OC- 2020-5361-00350

Differentiate.
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SWISS TECH INSIDE

Follow us:

HeiQ® AGS-20WP

An antimicrobial additive designed to withstand high temperatures in the manufacture of yarns, filaments, fibers, fiber masterbatches, textile-finishes, textile coatings and knitted, woven or nonwoven textile fabrics. Intended for commercial and industrial use, in manufacturing, formulating and fabricating of treated article products specified in the use directions.

Active Ingredient: Silver *	19.3 %
Other ingredients	80.7 %
TOTAL:	100.0 %

* includes particles in the size range between 1 and 100 nm.

EPA Reg. No-85249-1
EPA Est. 085248-CHE-00

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Harmful if inhaled, swallowed, or absorbed through skin. Avoid breathing dust. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

WORKER PROTECTION

Workers who mix, load, and apply (i.e., handling) **HeiQ® AGS-20WP** powder shall do so using engineering controls such as closed system loading or local exhaust ventilation. **HeiQ® AGS-20WP** powder cannot be applied using open pouring methods. The engineering controls shall provide, at the least, a 10 fold reduction in the concentration of airborne **HeiQ® AGS-20WP** powder as compared to the **HeiQ® AGS-20WP** powder concentration generated without engineering controls. In addition, workers exposed to powder are required to wear personal protective equipment including a full-face respirator with high-efficiency filter cartridges (i.e. PI00), gloves, a long-sleeve shirt, long pants, shoes plus socks, and overalls or a Tyvek® suit during powder handling. The gloves shall be chemically resistant to all of the components of the textile fiber master batch or coating formulations to which the HeiQ® AGS-20WP powder is added.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison center or doctor for treatment advice.
IF INHALED: Move the person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information on (product, use, etc.) call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, aquatic invertebrates, and birds. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
This product may not be used for any applications involving food contact, food packaging, or drinking water.

HeiQ® AGS-20WP is an antimicrobial additive for commercial and industrial use. It is designed to be incorporated into materials and intermediate polymer and coating solutions during the manufacturing process to impart durable antimicrobial and preserving activity to manufactured products. The product suppresses the growth of odor, stain, discoloration, degradation or contamination causing microbes. If microbial activity in the manufacturing product could lead to unpleasant odors, discoloration, deterioration or contamination of the product, then such claim may be made for the manufactured product. Manufactured products incorporating **HeiQ® AGS-20WP** may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product. When incorporated into treated articles, **HeiQ® AGS-20WP** does not protect users of any such manufactured product or others against food-borne or disease-causing bacteria, viruses, germs or other disease-causing organisms. treated articles **HeiQ® AGS-20WP** does not protect users of any such manufactured product or others against food-borne or disease-causing bacteria, viruses, germs or other disease-causing organisms.

HeiQ® AGS-20WP may be used in materials and intermediate polymer and coating and finishing solutions that may be incorporated into the treated articles listed below. For coating and finishing-type applications using solutions, the final textile article may contain a maximum of 0.0019% (by weight) of silver. For all other applications, the final textile article may contain from 0.001% to 0.01% (by weight) of silver. Contact HeiQ Materials AG to determine the appropriate amount of **HeiQ® AGS-20WP** for individual finished products.

NON-FOOD CONTACT USES

HeiQ® AGS-20WP may be incorporated into manufactured products listed below for non-food contact uses.

Textile Fibers and Fiber Coatings and Finishes: For use in/on natural and synthetic fibers and fabrics, including nonwovens fabrics, only in curtains; draperies; carpet underlay; mops; bags; wall covering fabrics; adult sleeping bags; filters; packaging; conveyor belts; automotive, aviation and truck
upholstery; rear decks; trunk liners; convertible tops and interior liners; umbrellas; clothing for adults (such as outerwear; uniforms; work gloves; aprons; sportswear; stockings; sport socks; hosiery; boxer briefs; tee-shirts; inner liners for jackets); shoes; helmets; artificial leather; book covers; cloth for sails; ropes; tents and other outdoor equipment; tarps, awnings.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage: Do not store in areas accessible to children. Keep containers covered and away from water and excessive moisture or humidity. Store at ambient temperatures.
Pesticide Disposal: Wastes from use of this product may be disposed of on site or at an approved disposal facility.
Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY STATEMENT

HeiQ Materials AG warrants that this product conforms to the chemical description on the label. HeiQ Materials AG makes no warranties of merchantability or fitness for a particular purpose or any other expressed or implied warranty except as stated above.

HeiQ Materials AG
Zürcherstrasse 42
CH-5330 Bad Zurzach
Switzerland
(347) 414-9113

HeiQ® Pure TAG

Broad Spectrum Biocide

Active Ingredient

Silver Chloride……..……2%
INERT INGREDIENTS……98%
TOTAL……100%

WARNING

KEEP OUT OF REACH OF CHILDREN

FIRST AID	
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
IF ON SKIN	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If Swallowed	• Call a poison control center or doctor immediately for treatment advice • Have person sip a glass of water if able to swallow • Do not induce vomiting unless told to do so by a poison control center or doctor • Do not give anything to an unconscious person
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-424-9300 in case of emergency.	

NET CONTENTS: 6.5 GAL

EPA Reg. No: 49403-38-85249
EPA Est. No. 72981-NC-001

Manufactured for:

HeiQ Materials AG
Zürcherstrasse 42
5330 Bad Zurzach
Aargau
Switzerland

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish, aquatic invertebrates, oysters, clam and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS
HeiQ® Pure TAG should not be used in formulations containing reducing agents, such as BHT, propyl gallate, ascorbic acid and derivates, as the silver ions would be reduced to metallic silver. This will result in discoloration to blue-grey-pink color and in loss of antimicrobial activity.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Heiq® Pure TAG is a stable, broad-spectrum biocide [developed for the protection of water-based products against fungi and bacteria in the wet state] [and][or] [for use in the manufacture of polymers, plastics, textiles and coatings]. HeiQ® Pure TAG is a broad-spectrum biocide that is effective over a wide pH range (pH 1 – pH 13). HeiQ® Pure TAG may be added at any stage in the processing. It is compatible in a wide range of formulations, and it is unaffected by the presence of particulate matter and most surfactants. Compatibility of Heiq® Pure TAG with the application should always be checked before use. Typical applications and the suggested range of concentrations on which trials can be based are outlined below; however, formulations vary and it is essential when first using Heiq® Pure TAG to first challenge test formulations before deciding on an optimum concentration.

Uses in textiles
Heiq® Pure TAG suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining, deterioration or corrosion only.
Manufactured products incorporating Heiq® Pure TAG may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product which permits such claims.

Manufactured products incorporating HeiQ® Pure TAG may not make any public health claims relating to antimicrobial activity without first obtaining an EPA registration for the manufactured product which permits such claims. When incorporated into treated articles, this product does not protect users of any such treated articles or others against food borne or disease-causing bacteria, viruses, germs or other disease-causing microorganisms.

Maximum Use Rate: 50,000 ppm of product (1000 ppm of silver chloride) by weight of goods (equivalent to 5 lb of product to 100 lb of goods)

Minimum use rate: 2,500 ppm of product (50 ppm of silver chloride) by weight of goods (equivalent to 0.25 lb product to 100 lb of goods).

[Minimum use rate California: 4000 ppm of product (80 ppm of silver chloride) by weight of goods (equivalent to 0.4 lb product to 100 lb of goods).]

APPLICATIONS (Not for use in any applications involving food contact, food packaging or human drinking water

APPLICATION	TYPES OF FINISHED PRODUCTS
Fibers and textiles	Napkins; wiping cloths; mops; towels; bags; brush bristles; filters; sponges; packaging including bags, sacks, wraps, cushion and absorbent materials, containers; conveyor belts (nonfood contact); apparel; commercial and industrial wipes and fabrics; Mattress cover pads and filling; pillow covers; sheets; blankets; towels; fiberfill for quilts and pillows; curtains; draperies; carpet and carpet underlay; rugs; upholstery; wall covering fabrics; cushion pads; sleeping bags; automotive and truck upholstery; carpeting; rear decks; trunk liners; convertible tops; interior liners; umbrellas; outerwear; apparel: sportswear; sleepwear; trim for outerwear and garments: stockings; socks; hosiery; caps; undergarments; inner liners for jackets; shoes; gloves and helmets; artificial leather; book covers; sails; ropes; tents and other outdoor equipment; tarps; awnings

STORAGE AND DISPOSAL:
Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE- Store in a dry place away from extreme heat and cold (tightly closed at +15ºC to +25ºC). Keep container closed when not in use. In the event of spillage or leakage, soak up material with absorbent clay, sand, sawdust, or other absorbent material. Scrape up and dispose of in accordance with the information given under PESTICIDE DISPOSAL. Repackage and relabel useable product in a sound container. In case of fire or other emergency, report at once by toll-free to 1-800-424-9300.
PESTICIDE DISPOSAL- Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING
[***For all except the Intermediate Bulk Container***]
This is a nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinse into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state or local authorities, by burning. If burned, stay out of smoke.

[***For the Intermediate Bulk Container***]
Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state or local authorities, by burning. If burned, stay out of smoke.

WARRANTY STATEMENT
HeiQ Materials AG warrants that this product conforms to the chemical description on the label. HeiQ Materials AG makes no warranties of merchantability or fitness for a particular purpose or any other expressed or implied warranty except as stated above.

Manufactured for:
HeiQ Materials AG
Zürcherstrasse 42
5330 Bad Zurzach
Aargau
Switzerland

HeiQ Viroblock

Treatment and mask testing questions

March 2020

SWISS TECH INSIDE

F A IA-OC 020-5361 00356

Questions

Physical Property and Chemistry:

Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device?

A. Applied as a topical surface treatment. Components of the treatment formulation remain coated to the outside of fibers durably thanks to a robust polyester resin based binder system covering each filament.

Use life:

What is the use life/performance life of the antimicrobial in this device?

The technology is ideally used for a one time use of disposable textiles used in critical environment such as hospitals. The EPA registered silver active is durable for over 50 washes on non disposable masks or other textile products.

Antimicrobial /Antiviral and other Performance Testing:

How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)?

Increased antiviral efficacy of treated face mask compared to control. Refer to Aerosol challenge test datset.

How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?

Mode of action is based on interaction with the surface treatment on the fibers and interaction with silver and vesicle coating components. Both the metallic silver and the vesicle are built to be non leaching technologies. Skin patch tests have been performed and resulted in non sensitizing.

Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?

Mask testing was conducted with standard laboratory test methods based on virus inoculation. Interaction with clinical soil was not simulated. The masks have been sold and use extensively during the Ebola crisis.

Questions

How many enveloped viruses were tested?
5 enveloped virus strains
(H1N1 (Human Influenza A); H5N1 (Avian Influenza A); 229E (Human Coronavirus); H7N9 (2013 Influenza A virus); RSV (Respiratory Syncytial Virus)

Is the technology effective against non-enveloped respiratory viruses?
Not tested to date. Peer reviewed literature indicates that the silver component is active against non-enveloped viruses.

Shelf Life and Stability:
What is the shelf life and stability of the antimicrobial in this device?
The silver component has a shelflife of up to 5 years. The vesicle technology has a shelf life of up to 2 years.

Does the device show a failed cytotoxicity score throughout the claimed shelf life?
Not tested to date. Based on the EPA testing dossier for the silver component, the skin patch tests and the literature it is reasonable to expect no advers cytotoxic effects during the shelflife.

Leaching Kinetics:
What is the rate of elution of antimicrobial in the device?
Leaching studies have been performed for the silver component on textiles. The EPA registered silver in use HeiQ AGS-20 is by far the least leaching silver form on the market today.

Questions

Biocompatibility Status:

Have you evaluated the biocompatibility status of this device?

Human patch testing. Non-sensitizing, Non-irritating (#).

Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives?

[Confidential] HeiQ Viroblock NPJ03 treatment components on a treated fabric basis (as applied in Human Patch test "sample 5" #):

Chemical basis	INCI name	CAS	g/kg fabric	% fabric
(2-hydroxypropyl)-beta-cyclodextrin	HYDROXYPROPYL CYCLODEXTRIN	128446-35-5	13.61	1.361%
Polyoxyethylene (2)cetyl ether	CETETH	9004-95-9	10.79	1.079%
Hexadecyltrimethylammonium bromide (*)	CETRIMONIUM BROMIDE	57-09-0	1.20	0.120%
Hexadecyltrimethylammonium chloride (*)	CETRIMONIUM CHLORIDE	112-02-7	1.20	0.120%
Dipropylene glycol	DIPROPYLENE GLYCOL	25265-71-8	0.95	0.095%
Cationic polyacrylate	POLYQUATERNIUM-37	26161-33-1	0.67	0.067%
Polyester polyol	POLYESTER	53637-25-5	0.56	0.056%
Guar gum	HYDROLYZED GUAR	9000-30-0	0.11	0.011%
Amorphous silica (**)	SILICA	112945-52-5	0.07	0.007%
Polypropyleneoxide & polyethyleneoxide block copolymer	-	109049-12-9	0.04	0.004%
Alcohols C12-14, ethoxylated	C12-14 pareth-15	68439-50-9	0.03	0.003%
Cocobis(2-hydroxyethyl) methylammonium chloride	PEG-2 COCOMONIUM CHLORIDE	70750-47-9	0.02	0.002%
Acetic acid	ACETIC ACID	64-19-7	0.02	0.002%
Silver (**)	CI 77820	7440-22-4	0.02	0.002%

Notes:

(*) Hexadecyltrimethylammonium chloride is used as an alternative to Hexadecyltrimethylammonium bromide for the USA

(**) EPA registered Silver chloride – titanium dioxide composite may be used as an alternative to EPA registered silver-silica composite

(#) 48 hour closed patch test under occlusion, Sample 5 (2011-1776 HEIQ POLYPROPYLENE NON-WOVEN FABRICS-5.pdf)

Questions

Please clarify if the device involves any nanoparticles or nano-technologies

Various forms of silver can be used in the HeiQ Viroblock NPJ03 treatment formulation including EPA registered nanocomposites of silver metal and silicon dioxide (HeiQ AGS-20) or alternatively EPA registered composite of silver chloride and titanium dioxide (JMAC PG Composite)

Differentiate.
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SWISS TECH INSIDE

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/7/2020 2:59:13 PM
To: Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]
CC: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: Would ask your review

Thanks you

From: Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 2:56 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Would ask your review

Dr. Kadlec,

Thank you for sending. I will get back to you soon.

Best,
Binita

Binita S. Ashar, MD, MBA, FACS
Director

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4680 |10903 New Hampshire Avenue | Silver Spring, MD 20993
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Binita.Ashar@fda.hhs.gov

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From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Tuesday, April 7, 2020 12:47 PM
To: Ashar, Binita S <Binita.Ashar@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Would ask your review

Binita- I received updated technical data that was shared to me by the consortium making the 3 ply cotton facial coverings impregnating them with an alternative antimicrobial compound. I would appreciate understanding if this compound is already subject to FDA review and approval or potentially eligible for EUA status. Any concerns comment sor recommdnations you would have. Best Bob

The Agion compound is what is being used.
<< File: Agion AM-B10G Slurry TDS Rev 0 (002).pdf >> << File: Agion Data File 03212020-V1.pdf >> << File: Agion Data File 03222020-Full.pptx >> << File: Redacted SARS Test Report.pdf >> << File: Gerba-Antiviral Properties of Agion.pdf >>

The proposed compound HeiQ
<< File: 20200320_ViroblockStudies_summary.pdf >> << File: AGS20WP lbl 21 02 2013 part 1.pdf >> << File: AGS20WP lbl 21 02 2013 part 2.pdf >> << File: HeiQ_ Pure TAG_ Final Label 2019 - Copy.pdf >> << File: HeiQViroblock_FDA_Questions.pdf >>
Thank you

Bob Kadlec

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/5/2020 8:40:03 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: [EXTERNAL] RE: Follow-up

Keagan and or Steve who would be appropriate to loop into this which is WALMART is willing to produce on scale cloth gowns and they seek a poc at FDA to coordinate on design cloth and treatment on such cloth is that Jeff Shueren?

From: Duffey, Michael P. EOP/OMB (b) (6)
Sent: Sunday, April 5, 2020 8:31 AM
To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Cc: OS Farmer, Robert (b) (6); Swartz, Nathan M (MIL) <(b) (6)>; Nelms, Jordan (DHS.GOV) (b) (6)>; Patrick Lake (b) (6)>
Subject: Fwd: [EXTERNAL] RE: Follow-up

Paul/Bob/Brian - I am helping WalMart shift their production to make gowns. Can you help point me toward an FDA POC who can help make their requests below happen?

Sent from my iPhone

Begin forwarded message:

From: Deanah Baker <Deanah.Baker@walmart.com>
Date: April 4, 2020 at 7:49:49 PM EDT
To: "Duffey, Michael P. EOP/OMB" <(b) (6)>, Doug McMillon <McMillon.Doug@walmart.com>
Subject: [EXTERNAL] RE: Follow-up

Mike,
The task force is working very hard to both secure any finished PPE gowns available and find alternative fabrics that can be used for PPE gown production going forward.
Unfortunately, we are not moving fast enough and we need your help to progress with speed. My ask is that you help us secure the actions below.

1. We need the FDA to waive the factory audits required for unregistered factories in order to buy PPE products on the spot.
2. We need a person from the FDA to approve new fabrics via two Zoom conference calls tomorrow and they must be lenient. Need approval same day so fabric creation can begin.
3. We need immediate trucking from any factory in China with found PPE gowns to the central pick-up of Operation Air Bridge. Who can help us with that?
4. We need to be able to fly gowns here from Central America as production is completed with the new fabrications from point #2.
5. We need the same FDA contact mentioned above to be a member of this task force going forward.

China is on holiday Sunday/Monday, but if we accomplish the above tomorrow, we will be prepared to move much faster, Tuesday, to immediately pick up any available inventory in the Chinese factories. We will also be able to quickly set up production of new gown fabrications in Central America.

I am available for a call anytime. (b) (6)
I will provide you a daily e-mail update as well.

Thank you,
Deanah

From: Duffey, Michael P. EOP/OMB <(b) (6)>
Sent: Saturday, April 4, 2020 4:47 PM
To: Deanah Baker <Deanah.Baker@walmart.com>; Doug McMillon <McMillon.Doug@walmart.com>
Subject: EXT: Follow-up

Doug/Deanah – I hope you are having a good Saturday. Just checking in to see how things are going and if there is anything further I can provide to help your efforts to ramp gown production.

Thank you again for your commitment to assist!

Sincerely,
Mike

_____

Mike Duffey
Program Associate Director for National Security Programs
Office of Management & Budget
The White House

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/7/2020 10:50:39 AM
To: Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]
CC: Marston, Barbara J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ae062e3e071488a9be7489fa12e5aa5-HHS-bxm5-cd]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d509580ef6419b926735f53a2fc3ae-HHS-Keagan.]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]
Subject: RE: 【外部メール】 Re: Conference call between Sec. Azar and Min. Kato Memo for the call

Erika when will this call occur? Timely and relavant to our ongoing efforts on the Grand Princess

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From: Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>
Sent: Saturday, March 7, 2020 10:14 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Redfield, Robert R. (CDC/OD) (b) (6) @cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) (b) (6) @cdc.gov>; Hahn, Stephen (FDA) <Stephen.Hahn@fda.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>
Cc: Marston, Barbara J. (CDC/DDPHSIS/CGH/DPDM) (b) (6) @cdc.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Lenihan, Keagan (HHS/IOS) <Keagan.Lenihan@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>
Subject: Fwd: 【外部メール】 Re: Conference call between Sec. Azar and Min. Kato Memo for the call

Dear colleagues-

Per the call this morning between Secretary Azar and Minister Kato, please find attached please find "**Environmental sampling for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during a coronavirus disease (COVID-19) outbreak aboard a commercial cruise ship: Preliminary Report**". We will follow up with

them to schedule a working level call. Please let Garrett and I know who from your team you would like to be part of that call.

Thanks so much for your kind attention to this on a Saturday.

Cheers,

Erika

———

Erika Elvander
Director, Asia and the Pacific
Office of Global Affairs, HHS
Sent from my iPhone

Begin forwarded message

From: 喜多 洋輔(kita-yousuke) <kita-yousuke@mhlw.go.jp>
Sent: Saturday, March 7, 2020 9:12 AM
To: Elvander, Erika (OS/OGA) <Erika.Elvander@hhs.gov>; Tignor, Beth (HHS/IOS) <Beth.Tignor@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Koo, Han (OS/OGA) (CTR) <Han.Koo@hhs.gov>; Callaghan-Arguelles, Christine (HHS/IOS) <Christine.Callaghan-arguelles@hhs.gov>
Cc: YOSHIDA TAKUNO <takuno.yoshida@mofa.go.jp>; 横堀 雄太(yokobori-yuuta.mi5) <yokobori-yuuta.mi5@mhlw.go.jp>; 松村 漠志(matsumura-hiroshi) <matsumura-hiroshi@mhlw.go.jp>; 堀内 日佐世(horiuchi-hisayo.ho8) <horiuchi-hisayo.ho8@mhlw.go.jp>; 野口 千彰(noguchi-chiaki.05y) <noguchi-chiaki.05y@mhlw.go.jp>; 乃村 久代(nomura-hisayo) <nomura-hisayo@mhlw.go.jp>; 佐原 康之(sahara-yasuyuki) <sahara-yasuyuki@mhlw.go.jp>; 平岩 勝(hiraiwa-masaru) <hiraiwa-masaru@mhlw.go.jp>; 田口 一穂(taguchi-kazuho.is5) <taguchi-kazuho.is5@mhlw.go.jp>
Subject: RE: 【外部メール】 Re: Conference call between Sec. Azar and Min. Kato Memo for the call

Dear Erika and US HHS colleagues

We appreciate you for today's ministerial call. As our minister mentioned in the call,

we would be very happy to have working level conference call, especially for the Grand Princess incident, if necessary.

Finally, please find the attached preliminary paper on the Diamond Princess environmental sampling results for your reference, in which

you can see survival rates of SARS-CoV-2 virus on the surface, pillows and so on. Really interesting results.

We believe this would also help you to find the way to cope with the Cruise ship.

Best wishes

KITA Yosuke MD MPH MPA
Senior Coordinator for Global Health
Ministry of Health Labor and Welfare of Japan
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Tel: +81 33 595 2404
Fax: +81 33 502 6678
1-2-2 Kasumigaseki Chiyoda Tokyo
100-8916 Japan

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/9/2020 12:35:08 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]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: Do you have a moment to chat ref EUA & PRep act?

Sent from my iPhone

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/12/2020 8:01:20 PM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d509580ef6419b926735f53a2fc3ae-HHS-Keagan.]
Subject: FYSA

S1 called Mayor DeBlasio called ref testing COVID-19 shortage of test kits and reagent. S1 asked Darcie to connect Tim atFDA to provide TA.

Sent from my iPhone

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/6/2020 7:55:36 PM
To: Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore
(SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov)
[Jon.krohmer@dot.gov]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Sellers, Angela C (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Lekan, Scott M (ACF)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Duncan, Blair B (OS)
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(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Toedt, Michael (IHS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Elvander, Erika (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kibunja, Julia (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo
(SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Bradsher, Kris (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Waters, Cicely (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Op Divs
[donald.rucker@hhs.govHHS]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Duncan, Blair B (OS)
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Arrieta, Jose (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Austin, Mary (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a7cf6c9efa46059390f7187ede675b-HHS-Mary.Au]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]

CC: Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Sauer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fea6337d521949a4b961ee21d11b3070-HHS-Michael]; Windom, Robert (OS/ASPR/EMMO) [Robert.Windom@hhs.gov]

Subject: COVID-19 HHS Response: Alignment of OPDIV/STAFDIV Activities

Importance: High

Dear HHS Colleagues,

Thank you (and/or your designee) for joining us on Wednesday. Convening the HHS OPDIVs and STAFFDIVs was an important step to maintaining open lines of communication in response to COVID-19. The information and feedback you provided my staff during the meeting will enable us to move forward together in our efforts to maintain the health care sector and strengthen its ability to protect patients, the health care workforce, and the public during the COVID-19 response.

During Wednesday's discussion, you shared your near-term top priorities, operational challenges, and support needs. This information will allow the Health Care System Resilience Task Force to identify opportunities for collaboration and potential gaps to be filled in the coming weeks. Some initial themes emerged from the meeting that we will follow up on. These include the need to:

- Increase situational awareness and collaboration within HHS and across USG agencies
  - Coordinate consistent responses to frequently asked questions
  - Align shared activities across the Department
- Align HHS components on guidance for modifying or delaying grant deliverables or requirements for HHS-associated grant programs
- Incorporate the needs of at-risk populations and those with access and functional needs in response and outreach efforts, including language translation
- Address supply chain challenges and limited availability of PPE and other supplies for the health care workforce
- Ensure continuity of HHS operations and HHS workforce safety during COVID-19 response

Several of you suggested to us that Wednesday's group should continue to meet on a regular basis as a forum to address ongoing operational and information-sharing demands during the COVID-19 response. Please save the tentative date of March 18, 2020 for our next meeting.

In the meantime, if you do not currently have representation on the following task forces, I invite you to identify a representative to join by submitting your representative's name, title, email address, and the task force they would like to sit on to ASPR.HCSRTF@hhs.gov by **Monday, March 9, at 5:00pm**.

- **The Health Care System Resilience Task Force** facilitates public-private sector collaboration to support ongoing response and mitigation efforts nationwide. The task force works to establish and maintain a common operating picture of health care system resilience, providing actionable decision support products to federal leaders and private sector partners. It typically convenes Tuesday and Thursday afternoons for an hour.

- **The Communications Task Force** coordinates public affairs, Congressional affairs and stakeholder engagement messages and activities relative to the COVID-19 outbreak. The Communications Task Force works closely with the all other response Task Forces while receiving strategic guidance from and feeding information to ASPA, ASL and IEA to help ensure alignment of efforts and awareness of activities across all HHS divisions.

If there is anything you need from ASPR or across HHS to help carry out your near term priorities, please let me know.

This is a critical juncture in time to align, synchronize and execute in a unified "One HHS" way to empower public and private actors at all levels to take the most effective action to contain and mitigate the impacts of COVID-19.

Thank you for your spirit of collaboration and commitment to save lives and protect Americans.

Respectfully,

Bob Kadlec
ASPR

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/15/2020 5:56:11 PM
To: Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-(b) (6)]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Tabak, Lawrence A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0037b2fbba164f33a24944311b80393e-HHS-Lawrenc]; Anderson, James M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7ae7a825549453d8398a1d93d3d7d21-HHS-james.a]; Santangelo, George M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ec58f11ceaa4e5693d795f544aecb4d-HHS-george.]
Subject: RE: Curated portfolio of preprints and publications on COVID-19

Thank you sir appreciate the link. Best Bob

From: Collins, Francis (NIH/OD) [E] (b) (6)
Sent: Wednesday, April 15, 2020 4:50 PM
To: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; 'sh1@fda.hhs.gov' <sh1@fda.hhs.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6); Anderson, James (NIH/OD) [E] Consult with HHS >; Santangelo, George (NIH/OD) [E] (b) (6)
Subject: Curated portfolio of preprints and publications on COVID-19

Dear Colleagues,

George Santangelo and his team members in our Office of Portfolio Analysis have developed a comprehensive, human-curated portfolio of COVID 19 publications and preprints: https://icite.od.nih.gov/covid19/search/ This includes peer-reviewed articles from PubMed and preprints from medRxiv, bioRxiv, ChemRxiv, and arXiv. It is updated daily and enables users to leverage the powerful iSearch platform to interrogate preprints, peer-reviewed publications, and all associated supplemental data from each. NIHers have found it extremely useful for querying what's already known about COVID 19 – so I thought I would pass it along to you also. Feel free to distribute!

Best, Francis

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/20/2020 6:44:39 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: (b) (6) 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]
Subject: RE: FDA Questions for your consideration re: Facemask

Thanks Steve and Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 20, 2020 6:03 AM
To: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin (FDA/OC) <Colin.Rom@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>; Lloyd, Lindsay (FDA/CDRH) <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 20, 2020 at 6:03:05 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) <adam.boehler@dfc.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

(b) (5). Can the appropriate person or persons from your office hop on a call at 10:30 or 11 AM today so we can get a better sense of the clinical settings and parameters for use for the mask? A little guidance would help.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>

Date: March 20, 2020 at 5:46:13 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: (b) (6) <(b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

Steve we have been trying to work a fast track to get these prototype fabric masks evaluated for non-health care setting initially and ask that we consider a fast track for eval. Or is this a NIOSH action

---

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:54 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: FW: FDA Questions for your consideration re: Facemask

FYI-

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:52 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Mr. Cook,

Thank you for the response email. Once your team has had an opportunity to look at the link to the guidance document, let me know if you still have questions as relates labeling. It would be helpful for the team to know the planned indications for use for the product. The indications for use will assist in your labeling.

Have a nice evening.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-
I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>

Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:

1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)

4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).

5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?

6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?

7. How many enveloped viruses were tested?

8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.

10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.

13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.

14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

Let me know if you have any questions or concerns.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Elizabeth.Claverie@fda.hhs.gov

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 6:03:28 AM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: (b) (6) 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Lloyd, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338a759166e74b13a5c9b385cde90eb9-Lindsay.Llo]
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 20, 2020 at 6:03:05 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

(b) (5). Can the appropriate person or persons from your office hop on a call at 10:30 or 11 AM today so we can get a better sense of the clinical settings and parameters for use for the mask? A little guidance would help.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 5:46:13 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) (b) (6) Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: [redacted] (b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

Steve we have been trying to work a fast track to get these prototype fabric masks evaluated for non-health care setting initially and ask that we consider a fast track for eval. Or is this a NIOSH action

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:54 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: FW: FDA Questions for your consideration re: Facemask

FYI-

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:52 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Mr. Cook,

Thank you for the response email. Once your team has had an opportunity to look at the link to the guidance document, let me know if you still have questions as relates labeling. It would be helpful for the team to know the planned indications for use for the product. The indications for use will assist in your labeling.

Have a nice evening.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1622&S=E

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-
I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:

1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)

4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).

5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?

6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?

7. How many enveloped viruses were tested?

8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.

10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.

13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.

14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

Let me know if you have any questions or concerns.

With Respect,

Liz

Elizabeth F. Claverie-Williams, MS

CAPT, USPHS-CC, Microbiologist

Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection

DHT4B: Division of Infection Control and Plastic Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: 301-796-6298

Elizabeth.Claverie@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1622&S=E

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/7/2020 7:42:15 PM
To: Franco, Celinda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0dec3ad5d69f4a75acc2c0ce99fba891-HHS-Celinda]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-[redacted] (b) (6)]; 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]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]
CC: Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Robinson, Wilma (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cb06883191e4f6e8d324d78743b27ad-HHS-Wilma.R]; Horska, Katerina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70fcf3bd050a4050931f28d7bf5f5f0f-HHS-Katerin]; Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Johnson, Ciara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03a290a2b5df49d0b06d9e98cf777cd5-HHS-Ciara.J]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]
Subject: RE: FLASH CLEARANCE: COVID-19 -- Remdesivir Options Paper

KADLEC ASPR CLEARS

From: Franco, Celinda (OS/IOS) <Celinda.Franco@hhs.gov>
Sent: Saturday, March 7, 2020 7:01 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; [redacted] (b) (6) Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>
Cc: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>; Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>; Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>; Johnson, Ciara (OS/IOS) <Ciara.Johnson@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Subject: FLASH CLEARANCE: COVID-19 -- Remdesivir Options Paper
Importance: High

All,

Please review and clear this document by 9:00 pm and submit comments to Celinda Franco.

Thank you,
Celinda
202.400.1924

From: Johnson, Ciara (OS/IOS) <Ciara.Johnson@hhs.gov>
Sent: Saturday, March 7, 2020 6:52 PM
To: Franco, Celinda (OS/IOS) <Celinda.Franco@hhs.gov>
Subject: FW: COVID-19 -- Remdesivir Options Paper -- FLASH CLEARANCE
Importance: High

FYI

From: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Sent: Saturday, March 7, 2020 6:24 PM
To: Johnson, Ciara (OS/IOS) <Ciara.Johnson@hhs.gov>
Cc: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; [redacted] (b) (6) Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>
Subject: COVID-19 -- Remdesivir Options Paper -- FLASH CLEARANCE
Importance: High

Ciara,

Following up on our call, NSC asked that HHS clear the attached options paper tonight (see below).

I understand that Dr. Kadlec had a call with Brian Cavanaugh on this topic, and advised that the HHS DLG run by Paul Mango would need to adjudicate this before HHS can clear. The NSC request is apparently coming from Cavanaugh.

This same options paper has gone through multiple rounds of informal clearance in the past 48 – 72 hours, and so apologies to the group for the repetitiveness of this. I am putting this through formal clearance with IOS, ASPR, FDA, OGC to ensure nothing falls through the cracks. I believe that I have copied all key stakeholders on this email.

Thanks,

Brian

On Mar 7, 2020, at 5:43 PM, Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov> wrote:

Will work to get this cleared tonight. With the cruise ship issues ongoing folks are spread thin. Brian

---

On: 07 March 2020 17:25,
"Jonas, Seth H. EOP/NSC" <Seth.H.Jonas@nsc.eop.gov> wrote:
Brian,

Brian C. asked if I could get this cleared tonight. Not sure what this means wrt WHTF. Do you except HHS to have any critics comments? A few typos were pointed out to me by others. I am working on fixing those.

Sorry for the short turn.

Thanks,
Seth.

On Mar 7, 2020, at 2:29 PM, Jonas, Seth H. EOP/NSC <Seth.H.Jonas@nsc.eop.gov> wrote:

Here's where we are right now on the document. I just sent it to my other EOP colleagues for comment. Your thoughts on which COAs are and are not recommended (by HHS) are appreciated.

Thanks,
Seth.

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/7/2020 9:28:42 PM
To: Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-[redacted] (b) (6)]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]
Subject: RE: Remdesivir Clinical Trial

The answer I know is the one Tony has stated. The Chinese study which was to enroll two 250 patient cohorts was nearing ~220 enrollees each and that it would be several months before the data of those two study groups would be released or shared and subject to release by the Chinese. Best Bob

---

From: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Sent: Saturday, March 7, 2020 8:58 PM
To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>
Subject: Remdesivir Clinical Trial

Do you know the answer to NSC's question below on clinical trials? Thanks, Brian

---

From: Jonas, Seth H. EOP/NSC <Seth.H.Jonas@nsc.eop.gov>
Sent: Saturday, March 7, 2020 1:31 PM
To: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Subject: RE: Question regarding Gilead

PS, also trying to sort out how soon the current Remdesivir trial could end, and/or expanded access could commence, if it is shown to be effective.

I pinged NIH on this also, but some of your folks might also know. [redacted] (b) (5)

Seth.

From: Jonas, Seth H. EOP/NSC
Sent: Saturday, March 7, 2020 1:26 PM
To: 'Stimson, Brian (HHS/OGC)' <Brian.Stimson@hhs.gov>
Subject: RE: Question regarding Gilead

Correct, no motion yet—though it has been reviewed by a number of senior staff, with broad concurrence. Some folks, however, wanted to better understand [redacted] (b) (5).

I am going to send an update of the doc out shortly (will include you on it). My understanding is that it might be queued up on Monday, pending Dr. Birx approval.

Seth.

From: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Sent: Saturday, March 7, 2020 1:22 PM
To: Jonas, Seth H. EOP/NSC <Seth.H.Jonas@nsc.eop.gov>
Subject: Re: Question regarding Gilead

No problem. Dumb question — from where you sit, no actions taken on this matter in the past 24 hours, correct? I have heard nothing new from ASPR on my end. Brian

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/10/2020 10:26:38 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Polowczyk, John P (MIL) (b) (6)]
Subject: RE: Would ask your review

Great thank you

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, April 10, 2020 10:24 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Polowczyk, John P (MIL) (b) (6)
Subject: Re: Would ask your review

Bob,
I believe you are up to date on this. Keagan and our group can update you so that Hanes has all of the information needed to manufacture gowns.
Thanks
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 9, 2020 at 5:12:46 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Polowczyk, John P (MIL) (b) (6)
Subject: FW: Would ask your review

Steve I wanted to let you know I have been working with Admiral P. on the cloth gowns with guess who? Hanes. They have a design that they are finalizing and they have suggested applying HeiQ VIroblock that would substitute for the copper-silver. This would help I think . I wanted to make you aware of this. It good advance the durability and address the issue of soiling. Best Bob

---

From: Kadlec, Robert (OS/ASPR/IO)
Sent: Tuesday, April 7, 2020 12:47 PM
To: Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; 'Hahn, Stephen' <SH1@fda.hhs.gov>
Subject: Would ask your review

Binita- I received updated technical data that was shared to me by the consortium making the 3 ply cotton facial coverings impregnating them with an alternative antimicrobial compound. I would appreciate understanding if this compound is already subject to FDA review and approval or potentially eligible for EUA status. Any concerns comment sor recommdnations you would have. Best Bob

The Agion compound is what is being used.

The proposed compound HeiQ

Thank you

Bob Kadlec

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/10/2020 11:39:06 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Polowczyk, John P (MIL) (b) (6)
Subject: RE: Would ask your review

Got it thanks.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, April 10, 2020 10:24 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Polowczyk, John P (MIL) (b) (6) >
Subject: Re: Would ask your review

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Steve

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Date: April 9, 2020 at 5:12:46 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Polowczyk, John P (MIL) (b) (6)
Subject: FW: Would ask your review

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---

From: Kadlec, Robert (OS/ASPR/IO)
Sent: Tuesday, April 7, 2020 12:47 PM
To: Ashar, Binita S (FDA/CDRH) <Binita.Ashar@fda.hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; 'Hahn, Stephen' <SH1@fda.hhs.gov>
Subject: Would ask your review

Binita- I received updated technical data that was shared to me by the consortium making the 3 ply cotton facial coverings impregnating them with an alternative antimicrobial compound. I would appreciate understanding if this compound is already subject to FDA review and approval or potentially eligible for EUA status. Any concerns comment sor recommdnations you would have. Best Bob

The Agion compound is what is being used.

The proposed compound HeiQ

Thank you

Bob Kadlec

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/5/2020 8:47:42 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: [EXTERNAL] RE: Follow-up

Have a great COVID Free day

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, April 5, 2020 8:47 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Follow-up

Thanks

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 5, 2020 at 8:46:29 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: Follow-up

Yes

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, April 5, 2020 8:46 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: Follow-up

Bob,
Keagan and I will route this morning.
Thanks for alerting us.
Is Ms. Baker from Walmart the appropriate person for us to contact?
Thanks again.
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: April 5, 2020 at 8:40:14 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: [EXTERNAL] RE: Follow-up

Keagan and or Steve who would be appropriate to loop into this which is WALMART is willing to produce on scale cloth gowns and they seek a poc at FDA to coordinate on design cloth and treatment on such cloth is that Jeff Shueren?

From: Duffey, Michael P. EOP/OMB <(b) (6) [redacted]>
Sent: Sunday, April 5, 2020 8:31 AM
To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>

Cc: OS Farmer, Robert (b) (6); Swartz, Nathan M (MIL) (b) (6); Nelms, Jordan (DHS.GOV) (b) (6); Patrick Lake (b) (6)
Subject: Fwd: [EXTERNAL] RE: Follow-up

Paul/Bob/Brian - I am helping WalMart shift their production to make gowns. Can you help point me toward an FDA POC who can help make their requests below happen?

Sent from my iPhone

Begin forwarded message:

From: Deanah Baker <Deanah.Baker@walmart.com>
Date: April 4, 2020 at 7:49:49 PM EDT
To: "Duffey, Michael P. EOP/OMB" <(b) (6)>, Doug McMillon <McMillon.Doug@walmart.com>
Subject: [EXTERNAL] RE: Follow-up

Mike,
The task force is working very hard to both secure any finished PPE gowns available and find alternative fabrics that can be used for PPE gown production going forward.
Unfortunately, we are not moving fast enough and we need your help to progress with speed. My ask is that you help us secure the actions below.

(b) (4)

I am available for a call anytime. (b) (6)
I will provide you a daily e-mail update as well.

Thank you,
Deanah

From: Duffey, Michael P. EOP/OMB Consult to OMB
Sent: Saturday, April 4, 2020 4:47 PM
To: Deanah Baker <Deanah.Baker@walmart.com>; Doug McMillon <McMillon.Doug@walmart.com>
Subject: EXT: Follow-up

Doug/Deanah – I hope you are having a good Saturday. Just checking in to see how things are going and if there is anything further I can provide to help your efforts to ramp gown production.

Thank you again for your commitment to assist!

Sincerely,
Mike

_____

Mike Duffey
Program Associate Director for National Security Programs
Office of Management & Budget
The White House

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/5/2020 8:46:24 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: [EXTERNAL] RE: Follow-up

Yes

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, April 5, 2020 8:46 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: [EXTERNAL] RE: Follow-up

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To: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Cc: OS Farmer, Robert <(b) (6) >; Swartz, Nathan M (MIL) (b) (6) ; Nelms, Jordan (DHS.GOV) (b) (6) >; Patrick Lake (b) (6) >
Subject: Fwd: [EXTERNAL] RE: Follow-up

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Begin forwarded message:

From: Deanah Baker <Deanah.Baker@walmart.com>
Date: April 4, 2020 at 7:49:49 PM EDT
To: "Duffey, Michael P. EOP/OMB" (b) (6) >, Doug McMillon <McMillon.Doug@walmart.com>
Subject: [EXTERNAL] RE: Follow-up

Mike,
The task force is working very hard to both secure any finished PPE gowns available and find alternative fabrics that can be used for PPE gown production going forward.
Unfortunately, we are not moving fast enough and we need your help to progress with speed. My ask is that you help us secure the actions below.

China is on holiday Sunday/Monday, but if we accomplish the above tomorrow, we will be prepared to move much faster, Tuesday, to immediately pick up any available inventory in the Chinese factories. We will also be able to quickly set up production of new gown fabrications in Central America.

I am available for a call anytime. (b) (6)
I will provide you a daily e-mail update as well.

Thank you,
Deanah

From: Duffey, Michael P. EOP/OMB <(b) (6)>
Sent: Saturday, April 4, 2020 4:47 PM
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Subject: EXT: Follow-up

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Sincerely,
Mike

_____

Mike Duffey
Program Associate Director for National Security Programs
Office of Management & Budget
The White House

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/5/2020 8:24:50 AM
To: Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1- (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a- (b) (6)]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011- (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344-H (b) (6)]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]
CC: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Windom, Robert (OS/ASPR/IO) [Robert.Windom@hhs.gov]
Subject: RE: COVID-19 Advisory Panel

All please note this meeting time will shift to 3:45 to deconflict with the White House Task Force meeting starting at 5 pm.

From: Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>
Sent: Saturday, April 4, 2020 7:35 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6); Conrad, Patricia (NIH/NIAID) [E] (b) (6) Collins, Francis (NIH/OD) [E] (b) (6) 'sh1@fda.hhs.gov' <sh1@fda.hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Bright, Rick

[redacted] (b) (6), Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) [redacted] (b) (6)>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Redfield, Robert R. (CDC/OD) (b) (6)@cdc.gov>; Strength-McGaughey, Tracie (CDC/DDNID/NCIPC/OD) (b) (6)@cdc.gov>; Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Callahan, Victoria (OS/ASPR/IO) (CTR) <Victoria.Callahan@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6)@cdc.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)
Cc: Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Windom, Robert (OS/ASPR/IO) <Robert.Windom@hhs.gov>
Subject: RE: COVID-19 Advisory Panel

Please see attached slide deck and background paper for the Advisory Panel meeting tomorrow afternoon.

<< File: BARDA COVID Vaccines White Paper 20200405.docx >> << File: BARDA COVID Portfolio Review 20200405.pptx >>
Chris

D. Christian Hassell, PhD
Senior Science Advisor
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
Washington, DC 20201

David.Hassell@hhs.gov

+1-202-692-4641 (office)
+1-202-295-7495 (mobile)

-----Original Appointment-----
From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Friday, April 3, 2020 1:57 PM
To: Kadlec, Robert (OS/ASPR/IO); Fauci, Anthony (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Collins, Francis (NIH/OD) [E]; 'sh1@fda.hhs.gov'; Dareshori, Zack (HHS/IOS); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary [redacted] (b) (6)); Ford-Barnes, Arwenthia (OS/ASPR/IO); [redacted] (b) (6)); Patrick, Vanessa [redacted] (b) (6)) (CTR); Moughalian, Jen (HHS/ASFR); Redfield, Robert R. (CDC/OD); Strength-McGaughey, Tracie (CDC/DDNID/NCIPC/OD); Hassell, David (Chris) (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Callahan, Victoria (OS/ASPR/IO) (CTR); Moreno, Rafael (OS/ASPR); Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Cc: Marks, Peter (FDA/CBER); Cochran, Norris (HHS/ASFR); Windom, Robert (OS/ASPR/IO)
Subject: COVID-19 Advisory Panel
When: Sunday, April 5, 2020 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: WEBEx -(b) (6)

- BARDA will present their portfolio and clear guidance

(Material/slide presentation forthcoming)

Hi Arwenthia Ford-Barnes,

Arwenthia Ford-Barnes updated this WebEx meeting for which you are an alternate host:

BARDA COVID-19 Advisory Panel Portfolio (on behalf of Dr. Robert Kadlec)
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
Start the meeting

When: Sunday, April 5, 2020, 4:00 pm (1 hr), Eastern Daylight Time (New York, GMT-04:00).

Access Information

Meeting Number:
999 853 846

Password:
(This meeting does not require a password.)

Host Key:
(b) (6) (Use this key during the meeting if you ever need to reclaim the host role.)

Audio Connection

(b) (6) (Meeting Server Main Number)

Access Code:
(b) (6)

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The meetingserver.hhs.gov team

Please excuse this mass email. I want to convey my greetings and best wishes from the Secretary who asked me to convene the Department's best people form CDC, NIH and FDA to periodically review, provide feedback and guidance to BARDA's COVID-19 MCM portfolio. I would expect this would be virtual and require read aheads providing detail of prospective programs in vaccines, therapeutics, diagnostics and potential medical devices. I would anticipate a first meeting in April and quarterly after that.

The challenge is you are all extremely busy and the only way this works is provide materials well in advance and conduct a substantive meeting in 60-75 minutes. I have had the chance to speak to some but not all of you and I apologize if I haven yet personally reached out to you on this topic. Again I appreciate your potential interest and willingness to help support a national crisis and national investment in finding safe and effective countermeasures. Best Bob

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/23/2020 8:33:15 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]
CC: Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; [redacted (b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1[redacted (b) (6)]]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]
Subject: Action Memo Concerning the Status of ICU/Ventilator related pharmaceuticals
Attachments: 18 Stockpile.docx

Mr. Commissioner and Mr. Adams:

I received this memo this evening from Dr. Navarro, Assistant to the President, requesting information concerning the status of supply of pharmaceuticals used in critical care setting for ventilator patients. I would respectfully request your attention and response and ask a suspense of COB Wednesday, 25 March 2020.

Thank you

Bob Kadlec
ASPR

MEMO TO ROBERT KADLEC, [redacted] (b) (6), MARC SHORT (FOR TASK FORCE)
FROM PETER NAVARRO
RE: CRITICAL DRUGS NEEDED FOR VENTILATOR SUPPORT OF COVID-19 PATIENTS IN INTENSIVE CARE UNITS (ICU)

The COVID-19 pandemic has caused an unusual, severe, and ever growing demand for invasive life-saving ICU mechanical ventilator support for use in infected patients. In addition, these invasive ventilated patients are maintained on mechanical ventilation from 1 to 2 weeks.

This has caused an increased and growing demand for the drugs needed by ICUs to support each patient on invasive mechanical ventilation. A recent review of drug availability in the Strategic National Stockpile reveals that none of these drugs may be stockpiled.

This status needs to be urgently confirmed or denied by the managers of the Strategic National Stockpile. If confirmed, the continuing availability of these drugs could conceivably become a major issue in the continuing COVID-19 response.

If there is no continuing ICU drugs of the type described below, there will be no invasive ICU ventilator management of patients in respiratory failure. All moderately severe patients will have to be non-invasively ventilated. Severe respiratory failure patients that require invasive ventilation will not receive this treatment and are expected to have a higher mortality rate.
Any shortage of these drugs will also have a major effect on some emergency and elective surgeries in non-COVID-19 patients.

RECOMMEND:

1. Urgent re-assessment of existing quantities of the drugs specifically listed in early February as being critical for the ICU management of COVID-19 patients (Appendix).

2. Reaffirmation that these drugs will continue to be available in large quantities for the next 3 months.

APPENDIX
DRUGS ESSENTIAL FOR INVASIVE VENTILLATOR SUPPORT

1. Atropine
2. Propofol
3. Vercuronium or Rocuronium
4. Fentanyl
5. Ketamine
6. Midazolam
7. Norepinepherine
8. Epinephrine
9. Suxamethonium

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/12/2020 8:59:25 PM
To: Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Mascola, John R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63aa50129c1f4d39bc0a31b3851a34c5-HHS-jmascol]; [redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1[redacted]]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; [redacted]) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-[redacted] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344[redacted]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]
Subject: Pursuant to My Email on Friday
Attachments: Vaccine strategy-200411-v 13.pptx; Secretary Determination Memorandum-Project Warp Speed-041120 1825 draft.doc

I want to share with you the product of the BCG team who drafted the attached briefing and Decision Memo drafted for the Secretary's review tomorrow. I want to thank all those who contributed over this holiday weekend to offer their ideas and concepts that is represented in these products. This represents just a first step of many steps that first outlines a concept that will then be operationalized into a historic effort for not only the Department and agencies who will contribute to it, but to our Nation. Again, thank you for your contributions and commitment. Best Bob

Project Warp Speed

Maximally expediting a safe, effective vaccine

APRIL 2020

0

A safe, effective, broadly-administered vaccine is the single most important solution to COVID-19 pandemic

MISSION: **Maximally expedite** the development of a safe and effective vaccine with sufficient scale to inoculate all Americans who need it

DEADLINE: Enable broad access to the public by **October 2020**

PLAN: Modeled after the **Manhattan Project** approach, a **multi-disciplinary, multi-sector team** that brings the numerous in-flight efforts under a **single authority** to drive relentless coordination, barrier elimination, and accountability for mission success

1

Notes view: 1

Strategic principles

Unprecedented circumstances…..

1. Return on Investment for an effective vaccine is "infinite"
2. No individual company can accrue the level of benefits that the country at large can
3. Unacceptably long timelines even with the best current approaches

….Requires an unprecedented business model

1. Take financial risk of excess unused capacity
2. Fail fast: be ruthlessly objective
3. Move from serial to parallel activities
4. Radical standardization, leveraging platforms for speed & efficiency
5. Shared services and prioritization towards the best opportunities
6. Elevate level of collaboration b/w industry, government academia - "one team"
7. Eliminate the "dead" time between phases/steps
8. Complete data transparency in making critical decisions

Notes view: 2

Key success factors

Organizational

Operating model stood up quickly, funding secured

Leader who will sustain public trust, with the right team

Empowered decision making, rapidly removing regulatory and funding barriers

100% dedicated team with appropriate **expertise** from government, industry and academia

Address any barriers to full industry participation: **share risk /reward, IP/Legal concerns**

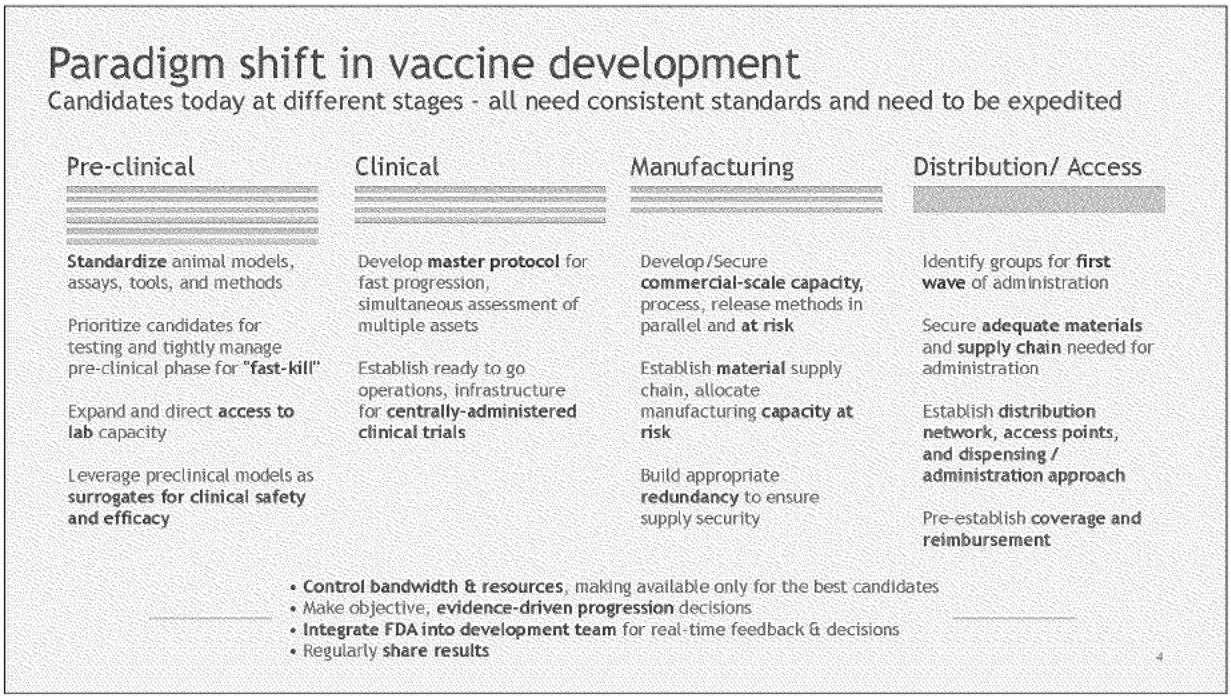
End-to-End

Challenge traditional Vx development approaches
- **FDA review integrated** into development

Quickly address the scarce, critical and costly capabilities
- Small **animal, NHP model capacity**
- **Manufacturing & supply chain capacity,** incl. raw material component, fill-finish, administration
- **Redundancy** for capacity and resilience

Proactively ensure vaccine can be **distributed, administered, reimbursed**

Notes view: 3


Paradigm shift in vaccine development
Candidates today at different stages - all need consistent standards and need to be expedited
Pre-clinical
Standardize animal models, assays, tools, and methods
Prioritize candidates for testing and tightly manage pre-clinical phase for "fast-kill"
Expand and direct access to lab capacity
Leverage preclinical models as surrogates for clinical safety and efficacy
Clinical
Develop master protocol for fast progression, simultaneous assessment of multiple assets
Establish ready to go operations, infrastructure for centrally-administered clinical trials
Manufacturing
Develop/Secure commercial-scale capacity, process, release methods in parallel and at risk
Establish material supply chain, allocate manufacturing capacity at risk
Build appropriate redundancy to ensure supply security
Distribution/ Access
Identify groups for first wave of administration
Secure adequate materials and supply chain needed for administration
Establish distribution network, access points, and dispensing / administration approach
Pre-establish coverage and reimbursement
• Control bandwidth & resources, making available only for the best candidates
• Make objective, evidence-driven progression decisions
• Integrate FDA into development team for real-time feedback & decisions
• Regularly share results
4

Notes view: 4

Developmental Milestones

• Validation of preclinical models confirmed	May 15, 2020
• Selection of lead candidates for further development	July 15, 2020
• Initiation of manufacturing at risk for vaccine & adjuvant	August 1, 2020
• Readout completed from Phase 1/2 studies	September 1, 2020
• Product fill completed for deployment in first vaccination campaign	September 15, 2020
• First 100M doses ready to vaccinate individual at risk under EUA	October 1, 2020
• Next 100M doses of vaccine available for next wave	November 1, 2020
• Total of 350M doses of vaccine available for all in need	Jan 1, 2021

5

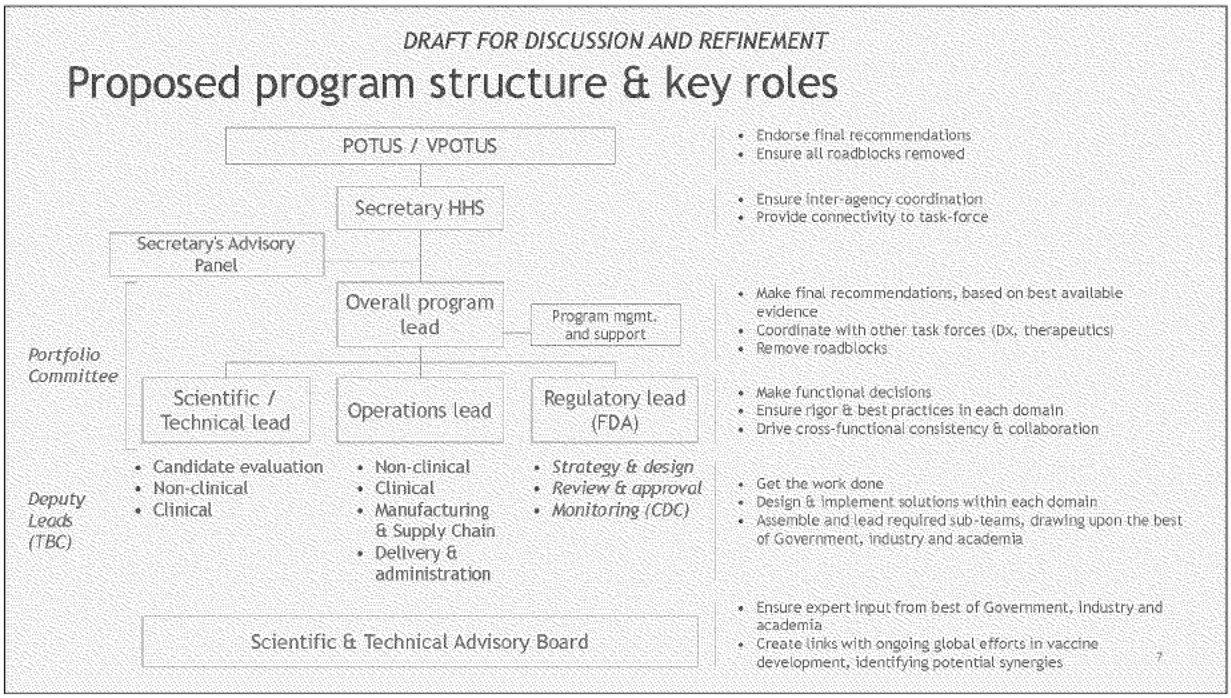
Notes view: 5

Many enablers must come together

Enablers	Roles
Government • HHS (lead agency): FDA, ASPR/BARDA, NIAID/VRC, NIAID/IRF, CDC • DoD: DTRA, MRMC, USAMRIID, VA • DHS: NBACC	• Lead & drive, as a unified front • Control the bandwidth & scarce resources • Provide funding & mitigate risks • Orchestrate stakeholders and remove barriers
Industry • Vaccine candidate developers - Select established players - Innovative pharma & biotech • R&D and Mfg services providers • Distribution & delivery partners	• Contribute vaccine candidates • Access the fastest / only route to market in the US • Provide R&D and manufacturing expertise & capacity • Share data & knowledge gained
Additional stakeholders • Academia • Multilaterals • Foundations/NGOs	• Contribute dedicated expertise and resources • Share data & knowledge gained • Coordinate global activities

6

Notes view: 6


DRAFT FOR DISCUSSION AND REFINEMENT
Proposed program structure & key roles
POTUS / VPOTUS
Secretary HHS
Secretary's Advisory Panel
Overall program lead
Program mgmt. and support
Portfolio Committee
Scientific / Technical lead
Operations lead
Regulatory lead (FDA)
Deputy Leads (TBC)
• Candidate evaluation
• Non-clinical
• Clinical
• Non-clinical
• Clinical
• Manufacturing & Supply Chain
• Delivery & administration
• Strategy & design
• Review & approval
• Monitoring (CDC)
Scientific & Technical Advisory Board
• Endorse final recommendations
• Ensure all roadblocks removed
• Ensure inter-agency coordination
• Provide connectivity to task-force
• Make final recommendations, based on best available evidence
• Coordinate with other task forces (Dx, therapeutics)
• Remove roadblocks
• Make functional decisions
• Ensure rigor & best practices in each domain
• Drive cross-functional consistency & collaboration
• Get the work done
• Design & implement solutions within each domain
• Assemble and lead required sub-teams, drawing upon the best of Government, industry and academia
• Ensure expert input from best of Government, industry and academia
• Create links with ongoing global efforts in vaccine development, identifying potential synergies
7

Notes view: 7

Next steps to implement

Immediately

1. Decisional memo
2. Establish the program structure and appoint leads
3. Engage priority stakeholders (internal and industry)
4. Understand and integrate existing programs and activities

Within the next 7 days

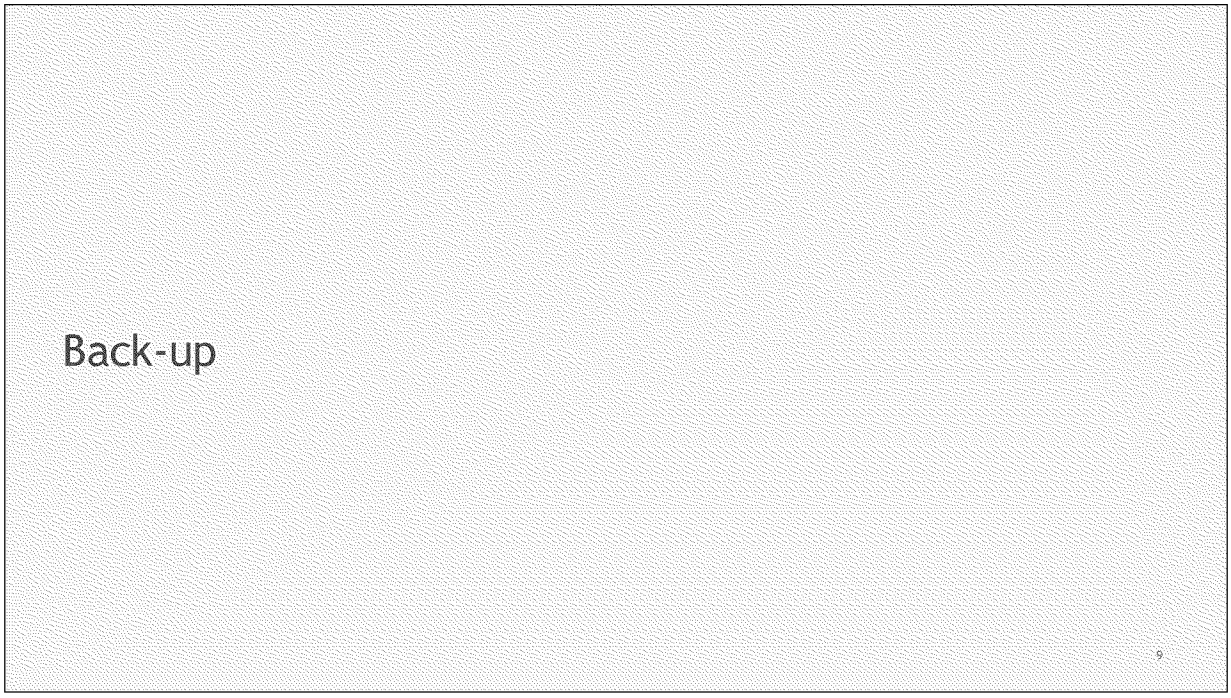
1. Engage all other relevant stakeholders
2. Develop a stage-gated budget and secure immediate funding to launch program
3. Appoint all key leads and supporting resources
4. Program plan with focus on immediate identification of scarce resources
5. Public messaging strategy, with considerations and options

What we need from you

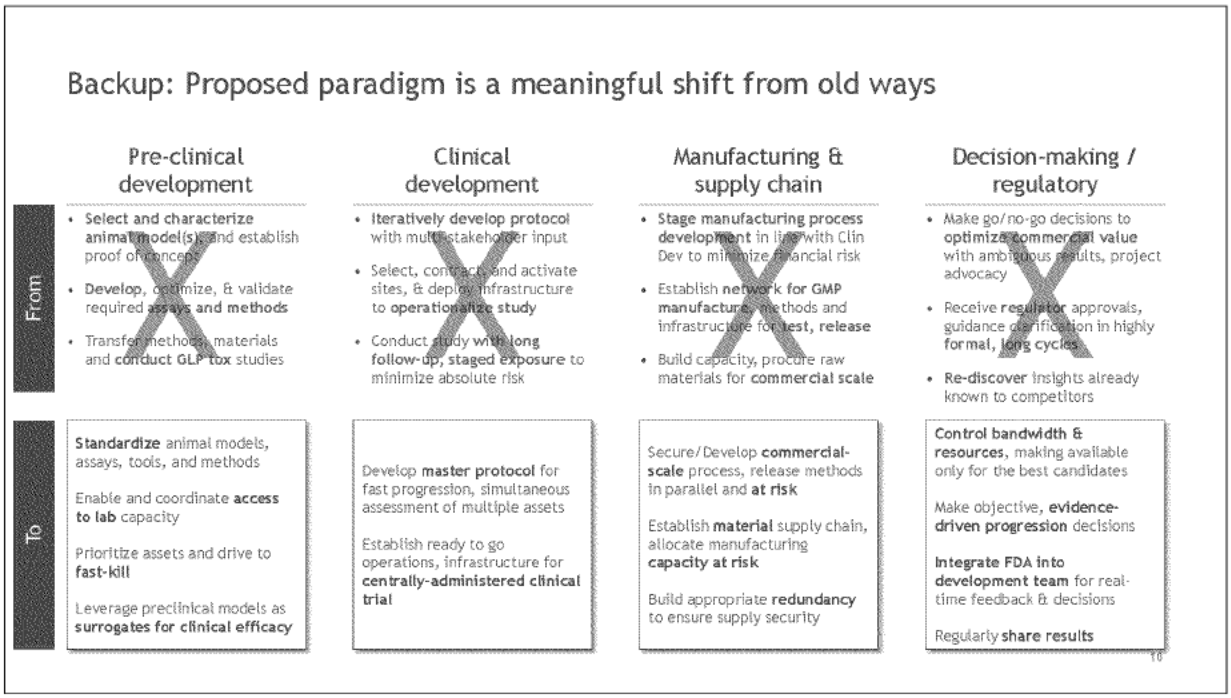
- Your endorsement
- Guidance on next formal steps
- Input on leadership roles

8

Notes view: 8



Notes view: 9



Notes view: 10

DRAFT FOR DISCUSSION AND REFINEMENT

Backup: Select decisions and accountabilities

Decision-maker	Select decisions and accountabilities
Portfolio committee • Overall lead • Scientific & Technical lead • Operations lead • Regulatory lead	• Approve Target Product Profile • Go/No-go at stage gates, including advancing candidates to clinical testing • Approve termination of candidates (no further central resources available to it) • Commit to manufacturing scale up for candidates • Determine manufacturing capacity to secure, and timing
Overall lead	• Secure and allocate overall project resources (budget, staff, facilities) • Facilitate and resolve any discrepancies between portfolio & operational decisions
Scientific & Technical lead	• Add new candidate to early-stage portfolio • Provide oversight to non-clinical and clinical activities • Recommend candidate advancement or termination to portfolio committee • Approve backup strategies for all candidates • Allocate preclinical, clinical, and manufacturing resources & capacity to candidates
Operations lead	• Secure & oversee preclinical capacity & resources (e.g., animals, labs) • Secure & oversee clinical trial sites & resources • Secure & oversee manufacturing capacity • Secure & oversee supply chain & raw materials • Secure & oversee supplies, capabilities & infrastructure for delivery
Regulatory lead (FDA)	• Approve regulatory strategies, design of platforms (preclinical, clinical, manufacturing) • Approve preclinical, clinical, manufacturing standards & requirements • Review and approve data & regulatory filings • Approve monitoring & surveillance plans

11

Notes view: 11

FDAFOIA-OC- 2020-5361-00419

TO: The Secretary
THROUGH: DS_____
COS_____
ES_____

FROM: Robert Kadlec, M.D., Assistant Secretary for Preparedness and Response
Peter Marks, M.D., Director, Center for Biologics Evaluation and Research

DATE: April 13, 2020

SUBJECT: Endorsement of ***Project Warp Speed*** to develop a safe and effective vaccine to prevent COVID-19 for broad deployment by October 1, 2020 – **DECISIONAL**

ISSUE

COVID-19 has presented an unprecedented challenge in U.S. modern history. Pending the development and deployment of an effective vaccine, most individuals in the country will remain susceptible to this virus and its resultant morbidity, mortality, and the nation will remain vulnerable to the associated social and significant economic disruption and national security risk. A fundamentally different approach to vaccine development is required to address the challenges presented by this pandemic. This approach will require clear operational leadership and lines of authority over parallel workstreams. Using a cross-sectoral approach leveraging the best available scientific and technologic expertise from across all of government, academia, and industry, the vaccine development and delivery playbook will be rewritten to facilitate the delivery of a safe, effective vaccine to a hundred million individuals judged to be at highest risk by October 1, 2020, and then ultimately to all those Americans who need it by January 1, 2020.

BACKGROUND

There is currently no effective vaccine against against SARS-CoV-2, nor is their even a highly effective treatment or prophylactic agent available. Though a few candidate vaccines are early in development, the current probability of success for deployment of a highly effective and safe vaccine to all Americans in need by January 1, 2020 is unacceptably low (estimate less than 5%). *Project Warp Speed* intends to accomplish the goal living by the motto: Failure is not an option.

The target goal is to produce 300 million doses of a safe and effective vaccine that protects at least 80% of the individuals who receive it against COVID-19. Ideally, this will be a one dose regimen that is easily deployed and effective within two weeks of administration leading to at least a year of protective immunity against the virus.

An extraordinary, collaborative vaccine development effort will be required that employs an iterative and aggressive, multi-candidate approach, with parallel development activity streams, transparency, data sharing within the team, aggressive manufacturing scale-up, risk management, streamlined regulatory approaches, and efficient delivery and dispensing of vaccine. Furthermore, sufficient funding is required both to conduct the nonclinical work that is critical to

the success of the approach, as well as to incentivize manufacturing partners to go 'all in' to prioritize time, capabilities, domestic manufacturing capacity, and to handle lost opportunity costs. In addition, funds will be required beyond research and development to support the subsequent vaccine availability, distribution and dispensing.

The approach relies upon the establishment of a fully integrated team with representatives from across government that will have an active role in different components of the end-to-end vaccine development and rollout process (the *Project Warp Speed* Team). The integrated project team will consist of full-time dedicated members of the various key agencies, with consultation from other government agencies as deemed appropriate. Clear lines of authority and decision-making capacity will be critical to allow multiple workstreams that usually are conducted in series to be moved onto parallel tracks. Non-clinical and clinical work will be conducted seamlessly. Manufacturing operations for the vaccines, any necessary adjuvants and supplies necessary for administration, as well as the establishment of a distribution system will all proceed at risk, guided by the best scientific information available.

The proposed organizational structure has the Secretary with the overall project lead reporting up through to the President and/or the Vice President, and an advisory panel of government agency leaders that will provide the Secretary regulatory, technical and public health policy advice. The Project Lead will report directly to the Secretary and will have decisional authority over the Scientific/Technical, Operational, and Regulatory project teams that will consist of appropriate sub-teams to effect the necessary work. Additionally, project security and the external flow of information will be carefully managed in collaboration with experienced government partners.

The timeline for the project are fully consistent with the moniker of *Project Warp Speed*:

Validation of preclinical models confirmed	May 15, 2020
Selection of lead candidates for further development	July 1, 2020
Initiation of manufacturing at risk	July 15, 2020
Readout completed from Phase 1/2 studies	August 1, 2020
Product fill completed for deployment in first vaccination campaign	September 15, 2020
First 100 million doses ready to vaccinate individual at risk under EUA	October 1, 2020
Next 100 million dose ready to vaccinate next wave	November 1, 2020
Total of 350 million doses available to vaccinate all in need in the US	January 1, 2021

RECOMMENDATION

We recommend that you approve the plan to proceed with obtaining the necessary human resources, logistic and financial support to activate *Project Warp Speed* as soon as possible.

Robert Kadlec, M.D.

Peter Marks, M.D.

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/10/2020 7:27:01 PM
To: Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Mascola, John R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63aa50129c1f4d39bc0a31b3851a34c5-HHS-jmascol]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-(b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-(b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-(b) (6)) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=041207dc34604bf2951e926363e5a344-(b) (6)]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Strength-McGaughey, Tracie (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a85aa10acd854ff69a6aff4106df6685-HHS-tmd9-cd]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-(b) (6).]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mark Hartell Consult with HHS [(b) (6) Mascola, John R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63aa50129c1f4d39bc0a31b3851a34c5-HHS-jmascol]; Suhana, Tina S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=071a954d7cb348f39d80d0bd64fb6a46-HHS-esuhana]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]

CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Kemp, Micha (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37e66d7934924dbbb481f43a55477be7-HHS-Micha.K]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]

Subject: RE: COVID-19 Advisory Panel Recommendations Following UP on Secretary Meeting this Am.

Importance: High

First thank you all for participating on Wednesday's evening call and producing the briefing memo for the Secretary's review. As a consequence of that meeting and discussion, he fully endorsed the recommendations of the vaccine portfolio you recommended. He, however, expressed, concern about the speed at which the companies of those candidates may be able to accelerate development and production to meet a potential "next wave" of COVID-19 in the fall.

The Secretary was informed of the draft of "Warp Speed" that will be included in his weekend reading. He asked that we consider developing an approach akin to the "Manhattan Project" for vaccines. Working with Paul Mango, we engaged the consultant company BCG to draft a high level approach to do so that we intend to share with the Secretary on Monday am. It is our intent to circulate that draft Sunday night for your awareness and comment. It will be only the first of several steps to organize a Whole of Government and Whole of Nation effort to identify, develop and produce a COVID-19 vaccine in 6 months.

This is an ambitious and challenging undertaking but one driven by the necessity to mitigate the public health, economic and national security threat this virus represents to our citizens, nation and our way of life. The Secretary is confident that together with our private sector partners this is achievable.

Have a restful holiday weekend.

Bob

From: Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>
Sent: Thursday, April 9, 2020 3:13 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] (b) (6) Collins, Francis (NIH/OD) [E] (b) (6); 'sh1@fda.hhs.gov' <sh1@fda.hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; (b) (6) Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>; (b) (6) Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Tignor, Beth (HHS/IOS) <Beth.Tignor@hhs.gov>; Redfield, Robert R. (CDC/OD) (b) (6)@cdc.gov>; Strength-McGaughey, Tracie (CDC/DDNID/NCIPC/OD) (b) (6)@cdc.gov>; Yeskey, Kevin

(OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Callahan, Victoria (OS/ASPR/IO) (CTR) <Victoria.Callahan@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Cochran, Norris (HHS/ASFR) <norris.cochran@hhs.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Windom, Robert (OS/ASPR/IO) <Robert.Windom@hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>; Holland, Tara (OS/ASPR/EMMO) <Tara.Holland@hhs.gov>; (b) (6) Gershman, Lynn E. (CDC/DDPHSIS/OD) <veu4@cdc.gov>; Kemp, Micha (OS/ASPR/MFHC) <Micha.Kemp@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Mark Hartel (b) (6) (b) (6) Mascola, John (NIH/VRC) [E] <(b) (6)>; Suhana, Tina (NIH/VRC) [E] (b) (6)>; Marston, Hilary (NIH/NIAID) [E] (b) (6); Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Subject: COVID-19 Advisory Panel Recommendations

Dear Panel members—

Secretary Azar requested a summary paper with a recommendation from the Panel re the BARDA vaccine portfolio. His deadline was 3:30pm today.

Based on the discussion last night and other discussions with the BARDA team, the summary highlights the 5 vaccines that had concurrence. Please let me know as soon as possible if this is not the case.

Apologies for the fast turn. Thank you again for your participation in the Panel.

Chris
<< File: COVID Vaccines Briefing Memo V.3.docx >>

-----Original Appointment-----
From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Monday, April 6, 2020 1:36 PM
To: Kadlec, Robert (OS/ASPR/IO); Conrad, Patricia (NIH/NIAID) [E]; Collins, Francis (NIH/OD) [E]; 'sh1@fda.hhs.gov'; Dareshori, Zack (HHS/IOS); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Ford-Barnes, Arwenthia (OS/ASPR/IO); (b) (6) Moughalian, Jen (HHS/ASFR); Shuy, Bryan (OS/ASPR/IO); Redd, John (OS/ASPR/SPPR); Tignor, Beth (HHS/IOS); Redfield, Robert R. (CDC/OD); Strength-McGaughey, Tracie (CDC/DDNID/NCIPC/OD); Hassell, David (Chris) (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Callahan, Victoria (OS/ASPR/IO) (CTR); Moreno, Rafael (OS/ASPR); Marks, Peter (FDA/CBER); Cochran, Norris (HHS/ASFR); Messonnier, Nancy (CDC/DDID/NCIRD/OD); Windom, Robert (OS/ASPR/IO); Lane, Cliff (NIH/NIAID) [E]; Holland, Tara (OS/ASPR/EMMO); Johnson, Robert (OS/ASPR/BARDA); Gershman, Lynn E. (CDC/DDPHSIS/OD); Kemp, Micha (OS/ASPR/MFHC); Lenihan, Keagan (FDA/OC); Mark Hartell (b) (6); Mascola, John (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Marston, Hilary (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]
Subject: #2 - COVID-19 Advisory Panel
When: Wednesday, April 8, 2020 5:15 PM-6:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: WEBEx - (b) (6) 9

Presentation for Wednesday. THIS IS THE UPDATED VERSION 4:26pm
<< File: BARDA COVID Vaccines White Paper 20200405b.docx >>
Meeting Objective:
(1) Complete review of BARDA vaccine portfolio (to include related NIH and DoD programs), with emphasis on discussion among Panel members;
(2) Formulate a recommendation to Secretary Azar to either endorse or modify current vaccine strategy, plans, proposed funding and contracts.

Agenda
Brief review of vaccine programs

- BARDA (deeper dive after Sunday overview)
- NIAID
- DoD

Discussion
Recommendation to Secretary Azar

For convenience, below are the presentation and White Paper from last Sunday evening.
<< File: BARDA COVID Portfolio Review 20200405b.pptx >> << File: Vaccine Discussion with S1 and HHS Leadership V2 FINAL - [redacted] >

Hi Arwenthia Ford-Barnes,

You updated this WebEx meeting:

#2 COVID-19 Advisory Panel on behalf of Dr. Robert Kadlec
Host: Arwenthia Ford-Barnes

When it's time, start your meeting from here:
Start the meeting

When: Wednesday, April 8, 2020, 5:15 pm (1 hr 15 mins), Eastern Daylight Time (New York, GMT-04:00).

Access Information

Meeting Number:
(b) (6)

Password:
(This meeting does not require a password.)

Host Key:
(b) (6) (Use this key during the meeting if you ever need to reclaim the host role.)

Audio Connection

(b) (6) (Meeting Server Main Number)

Access Code:
(b) (6)

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<< File: BARDA COVID Vaccines White Paper 20200405b.docx >> << File: BARDA COVID Portfolio Review 20200405b.pptx >> << File: Vaccine Discussion with S1 and HHS Leadership V2 FINAL - (b) (6).pdf >>

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/23/2020 8:21:45 PM
To: Navarro, Peter K. EOP/WHO [Peter.K.Navarro@who.eop.gov]; Boehler, Adam [(b) (6)
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; OS Bibo, David (b) (6); Penn, Damon (fema.dhs.gov) (b) (6); Dorko, Jeffrey (fema.dhs.gov) (b) (6) Gaynor, Pete (fema.dhs.gov) (b) (6)]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: RE: HIGH IMPORTANCE 2M SURGICAL GOWNS AVAILABLE

Peter lets consider sending 500 K to WA, CA and NY and reserve 500K. Is there a POC at CARDINAL who can facilitate distribution directly to the States listed. I f there is a dissenting view from the team copied please indicate. Best Bob

---

From: Navarro, Peter K. EOP/WHO <(b) (6)>
Sent: Monday, March 23, 2020 7:16 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Boehler, Adam (b) (6)
Subject: HIGH IMPORTANCE 2M SURGICAL GOWNS AVAILABLE

3.23.20

MEMO TO BOB KADLEC, ADAM BOEHLER
FROM PETER NAVARRO
RE: DONATION OF 2M SURGICAL GOWNS FOR USE AS ISOLATION GOWNS

Cardinal Health has generously offered to immediately donate 2M recalled AAMI Level 3 surgical gowns to the Strategic National Stockpile and FEMA The gowns were recalled because they were manufactured at sites that could not guarantee they were suitable for surgical units. However, they should be perfectly usable as isolation gowns and Cardinal has tested several hundred and found them free of defects.

If this is acceptable, please let me know exactly where the gowns should be sent. I can have them in inventory within a day. We should start distributing them immediately to NYC, WA, and CA.

Navarro

P.S. FDA might need to provide and EUA to repurpose the gowns

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/19/2020 12:44:26 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: lou.hayden@lowes.com
Subject: Fwd: Request for expedited FDA action for Hand Sanitizer - Moxie

Steve can you advise who Mr Hayden from Lowe's could connect with th expedite review and approval

Sent from my iPhone

Begin forwarded message:

From: "Hayden, Lou" <lou.hayden@lowes.com>
Date: March 19, 2020 at 12:38:21 PM EDT
To: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Subject: Request for expedited FDA action for Hand Sanitizer - Moxie

Hello Dr. Kadlec – Good to talk with you briefly. During our CEO's call with the President on Tuesday, they asked for contact if we needed help on critical items.

Situation:
We have a found viable source for hand sanitizer out of Mexico and have validated their products. The quickest path to shelf/market is under our Private label Moxie. The vendor brand is registered only in Mexico, not in the US and this registration would take longer. Our Quality Assurance and Legal teams say that it will take 14 - 20 business days for the FDA to assign a labeler code (FDA certification number) and approval of our product label.

Ask:
Is there a contact we can work with at the FDA to expedite this process?

Please let me know how I can help.

Lowe's has 1,750 stores around the U.S. and 300,000 employees, and our products are "essential" for executing social distancing.

With warm regards,

Lou

Lou Hayden
Head of Washington, DC Office
Lowe's Companies
300 New Jersey Avenue NW, Ste. 900
Washington, DC 20001
202-464-2780

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 9:56:58 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Navarro, Peter K. EOP/WHO [Peter.K.Navarro@who.eop.gov]; christopher.j.abbott@who.eop.gov
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]
Subject: FW: EXSUM #2 - DoD 0915, 16 March
Attachments: EXSUM_MILAIR Support for COVID 19 Response.docx; EXSUM_MILAIR 2 Support for COVID 19 Response_16 Mar 2020.docx

FYSA please not MILAIR 2 as the most up to date status

From: Hann, Ronald K Jr SES DTRA R AND D (USA) <r(b) (6)>
Sent: Monday, March 16, 2020 9:26 AM
To: Oxford, Vayl S SES DTRA J0 (US) (b) (6)>; Shaffer, Alan R HON OSD OUSD A-S (USA) (b) (6)>; Rogers, Darsie D Jr LTG USARMY DTRA J0 (US) <(b) (6) Williams, Rhys M SES DTRA R AND D (USA) (b) (6); Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Cc: Froude, Jeffrey W MAJ USARMY DTRA J9 (USA) (b) (6)>; Havens, Jeffrey A MAJ USARMY DTRA R AND D (USA) <(b) (6)l>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Vann, Brandi C SES OSD OUSD A-S (USA) <b(b) (6)l>
Subject: EXSUM #2 - DoD 0915, 16 March

Team,
Attached is EXSUM #2 capturing current status of our mission. Also attached is the EXSUM from yesterday for those that may not have seen it. Note, there are photos on the third page. Top left is typical Air Force humor!

The bird is in the air to Ramstein AFB as I type. Let me know if you have questions.

v/r,
Ron

Ronald K. Hann, Jr., PhD, SES
Director
Chemical and Biological Technologies Department
Defense Threat Reduction Agency
(571) 616-4704

EXSUM: MILAIR Request to Support National COVID 19 Response as of: 1130 hrs, 15 March 2020

Background.

Copan Diagnostics, located in Brescia BS, Italy, is the primary supplier for diagnostic swab kits for Corona virus (COVID-19) needed by the FDA. POTUS announced on Friday, 13 Mar that a "drive thru" diagnostic capability would be established for the U.S.. Due to supply chain limitations in Italy, an adequate supply of these diagnostic materials is in question to meet our National requirements.

Current Status:

DTRA received an initial inquiry from HHS on Friday, 13 March, asking if DoD could potentially support a MILAIR mission to immediately transport a bulk shipment of diagnostic swabs from Italy. This request was made in part thanks to a previous mission we had coordinated to transport bulk Ebola vaccine from Germany to the U.S. to support outbreak operations in the Congo. The DTRA team initiated contact with TRANSCOM to define tentative mission parameters while notifying senior leaders of the possible mission. Initial plans for this air movement were in place by Friday evening. A formal request from HHS was not made on Friday.

Around 2000 hours, Saturday, 14 March, Chris Abbot from NSC requested DoD's support in conducting a MILAIR request to support HHS. His call was almost immediately followed by Peter Navarro, Special Assistant to POTUS, who stated the full authority of the White House was behind the request.

The DTRA team coordinated overnight with TRANSCOM, HHS, FDA and Copan Diagnostics to execute this mission. Coordination efforts at this point include:

- USTRANSCOM is prepared to execute the mission. All paperwork and funding requirements are complete for a first mission. Additional funding will be required to cover a sustained operation. The DTRA/HHS IAA is under modification right now to increase the current cap to support this mission worldwide if necessary.

- Aviano AFB has been contacted and is standing by for further orders.

- Copan Diagnostics sent a first shipment of diagnostic swabs on Friday via commercial air freight. We have shipping invoices and are in contact with FDA who is working to lock down the location. It does not appear that this shipment is in a "lost cargo" status, i.e., FDA will locate it and continue to move that shipment into the medical response system

- FDA requests that we proceed with MILAIR to pick up a second shipment of material that is currently under manufacture/production. Travel restrictions within Italy remain a limiting factor toward achieving US demand signal. We may need to establish an air bridge for a period of time until commercial/freight air flow out of Italy is reestablished or stabilizes.

- The second shipment is expected to arrive at Aviano AFB on Monday evening at 2200 hrs (local), 1400 hours EST (8 hours' time difference). Based on when cargo will be available to pick up, DTRA's team will prepare and package the cargo onto 13 each 463L pallets (2-4 hours). There are approximately 500,000 test kits. All will be manifested, documented, and loaded onto a C-17 with a destination of March AFB, CA (Riverside). We will discharge the cargo and send it to a distribution center an hour from March AFB for breakdown and forward movement throughout the U.S..

- NSC and WH are stressing speed and have asked us to explore the potential to get a partial shipment sooner than our current timeline. DTRA is working with TRANSCOM to have a C-17 in flight to Andrews AFB within the next 90 minutes. That flight will refuel and be joined by the DTRA team. We will have an aircraft on the ground waiting for the material. The limiting factor will be Copan Diagnostics. The company needs to agree to deliver a partial shipment and coordinate that timeline. FDA is in contact with the company now, but is concerned that they may not get the required export shipping paperwork completed in time to do an earlier partial shipment since they are working on a Sunday. We will continue to explore this option.

- An additional shipment is in planning for later this week, with the team departing Thursday or Friday.

Prepared by: Ron Hann, [HYPERLINK "mailto:Ronald.k.hann2.civ@mail.mil"] , w. (571) 616-4852 or c. (571) 408-0086

EXSUM: MILAIR #2 Request to Support National COVID 19 Response
as of: 0915 hrs (EST), 16 March 2020

Background.

Copan Diagnostics, located in Brescia BS, Italy, is a primary supplier for diagnostic swab kits for Corona virus (COVID-19) needed by the FDA. POTUS announced on Friday, 13 March that a "drive thru" diagnostic capability would be established for the U.S.. Due to supply chain transportation limitations in Italy, an adequate supply of these diagnostic materials is in question to meet our National requirements. DTRA initiated an airlift request through TRANSCOM for these materials beginning Saturday, 14 March at 2000 hours.

Current Status:

A USTRANSCOM C-17 loaded pallets at Aviano AFB, Italy and departed for Ramstein AFB at 0806 hours (EST), 16 March. There, the crew will go into crew rest for 7 hours. Expected delivery to Copan Diagnostics at Memphis International Airport is around 0200 CST, Tues, 17 March. A portion of the first shipment of diagnostic material was located this morning, 16 March by the FDA in Milan. This cargo was originally bound for Frankfurt to arrive in the U.S. on Wed., 18 March. This cargo will be diverted to Aviano and packaged for air movement with a third shipment of material on Thurs, 19 March.

Timeline of Events:

The majority of Sunday, 15 March was spent on mission planning and initial execution of the air mission to Aviano AFB, Italy. During the day, Chris Abbott, NSC advisor, provided input and mission guidance as information developed in the WH situation room.

TRANSCOM approved flight plans early morning on 15 MAR and a C-17 was secured out of McGuire AFB, NJ to pick up DTRA crew at Andrews AFB. Following an initial delay for maintenance, the C-17 departed McGuire AFB at approximately 1700 EST, with a subsequent departure from Andrews AFB 1822 EST bound for Ramstein AFB.

Upon arrival in Ramstein, the airframe developed a maintenance challenge resulting in an aircraft change and additional delay of two hours. The flight departed Ramstein with a new crew and aircraft at 0424 EST.

The team arrived at Aviano AFB at 0559 EST, and a team from the USAF, the 724 AWS "PortDawgs," rapidly loaded seventeen 463L pallets onto the aircraft. The "PortDawgs", led by MSgt Joseph Pendland, received 52 commercial pallets earlier in the day from the Copan Diagnostics and worked to package these for manifest and load onto the C-17. The C-17 departed Aviano at 0806 EST with destination of Ramstein AFB to retrieve trans-atlantic crew, and original aircraft. Due to crew restrictions, the team will be on ground for several hours before departure to Memphis (MEM) with expected time of arrival in MEM of 0200 CST, 17 March.

FEDEX joined the team late in the afternoon Sunday, leading to an APOD change from March AFB, CA to Memphis, TN. Upon arrival of USTRANSCOM C-17 at Memphis, Copan Diagnostics will inventory

the cargo and sign over to the FDA. The on-site team will then assist in breaking down the cargo into smaller packages for same-day delivery via FEDEX to six states and 10 locations.

DTRA recommends DHHS SEC formally submit a Request for Assistance (RFA) to DoD to establish a direct line of coordination with TRANSCOM. DTRA is currently sitting in the middle of the coordination process because it had an Inter-Agency Agreement (IAA) with DHHS from a previous air mission to ship bulk Ebola vaccine. The cap on the IAA is rapidly approaching its funding limit. Following a coordination call this morning at 0700, DHHS will facilitate the formal agreement between DHHS and Air Mobility Command (AMC). If the agreement is not established in time to support the next mission on 19 MAR, DTRA can assist, however it is a less efficient process.

Prepared by: Ron Hann, PhD, SES, [HYPERLINK "mailto:ronald.k.hann2.civ@mail.mil"] , w. (571) 616-4852 or c. (571) 408-0086 , Director, Chemical and Biological Technology Office, Defense Threat Reduction Agency


164 AW
FLIGHT TRAIN
TO MEMPHIS

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/1/2020 6:17:21 AM
To: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; 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]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]
CC: Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]
Subject: RE:

Thanks Brian Chris Hassel my Science Advisor copied here is my guy . He has engaged with DOE Science but I will have him follow up. Best Bob

---

From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Sunday, March 1, 2020 6:10 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Cc: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>
Subject: FW:

The Secretary of Energy called me Friday night and offered assistance. Specifically, he said that he cleared out capacity on his super computing systems if that would be of any help to us.

Also, he sent this attached report on potential therapeutics. Would you please have your right SMEs review and follow up with me.

Thanks,

Brian

From: Brouillette, Dan
Sent: Friday, February 28, 2020 9:58 PM
To: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Subject:

Brian:

As we discussed earlier this evening, here's a preliminary finding from scientists at Oak Ridge National Laboratory using the Summit supercomputer system. We stand ready to assist in any manner helpful to you and Secretary Azar. Very best,

Dan

Sent with BlackBerry Work
(www.blackberry.com)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/30/2020 6:50:23 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: THe S2 called me

Bob,
It's really helpful for cycling of respirators which is what the current EUA is about. My electrons, do you mean background info?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 29, 2020 at 9:31:34 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: THe S2 called me

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 2:32:30 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; (b) (6) 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ashar, Binita S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=163dac785c1641709451a95afbc3edec-BSA]; Debi Birx MD [Deborah.L.Birx@nsc.eop.gov]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Jeff. Well done.
Steve

Sent from my iPad

On Mar 20, 2020, at 2:30 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

I wanted to let you know that we just got off the phone with the company. We found a glidepath for them to come to market now that would allow them to also market directly to healthcare facilities and healthcare workers with just a few disclaimers in their labeling and nothing else for them to do. They liked the idea. We're sharing that language with them now and otherwise they are good to go. They tell us they should be able to produce between (b) (4) masks per week starting in about two weeks and the possibility of being able to (b) (4)

Jeff

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 20, 2020 at 6:03:04 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) (b) (6) Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ashar, Binita S <Binita.Ashar@fda.hhs.gov>, Lloyd, Lindsay <Lindsay.Lloyd@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

(b) (5). Can the appropriate person or persons from your office hop on a call at 10:30 or 11 AM today so we can get a better sense of the clinical settings and parameters for use for the mask? A little guidance would help.

Jeff

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: March 20, 2020 at 5:46:13 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Cc: [redacted] (b) (6) Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: [redacted] (b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

Steve we have been trying to work a fast track to get these prototype fabric masks evaluated for non-health care setting initially and ask that we consider a fast track for eval. Or is this a NIOSH action

---

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:54 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: FW: FDA Questions for your consideration re: Facemask

FYI-

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:52 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Mr. Cook,

Thank you for the response email. Once your team has had an opportunity to look at the link to the guidance document, let me know if you still have questions as relates labeling. It would be helpful for the team to know the planned indications for use for the product. The indications for use will assist in your labeling.

Have a nice evening.

With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1622&S=E

From: Cook, Jerry <Jerry.Cook@hanes.com>
Sent: Thursday, March 19, 2020 5:46 PM
To: Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>

Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>
Subject: RE: FDA Questions for your consideration re: Facemask

Thank you-

I will circulate to the team to get quick answers back.

Right now, we do not have any plans for labels, so if you have a requirement/suggestion-please let us know.

From: Claverie, Elizabeth F [mailto:Elizabeth.Claverie@fda.hhs.gov]
Sent: Thursday, March 19, 2020 5:40 PM
To: Cook, Jerry <Jerry.Cook@hanes.com>
Cc: Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Panguluri, Ramesh K <Ramesh.Panguluri@fda.hhs.gov>; Murray III, Clarence <Clarence.Murray@fda.hhs.gov>; Qian, Bifeng <Bifeng.Qian@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>
Subject: FDA Questions for your consideration re: Facemask

Dear Mr. Cook,

Please see below questions from our infection control team for your consideration:

Physical Property and Chemistry:

1. Please discuss how the antimicrobial is partition in the device. More specifically, is the antimicrobial embedded within the fibers of the device or is it coated on the device.

Use life:

2. What is the use life/performance life of the antimicrobial in this device

Antimicrobial /Antiviral and other Performance Testing:

3. How does this device performance testing compare in comparison to surgical facemask (Δp, fluid resistance, filtration efficiency)

4. The firm should clarify whether the masks have both types of coatings (HeIQ Vessicle technology and Agion technology).

5. How are the Vessicles coated impregnated in the device and would they leach out of the fabric for its action?

6. Antiviral testing performed under the conditions of use of the device (in other words, does the presence of clinical soil such as sweat and mucous decrease the antiviral effectiveness)?

7. How many enveloped viruses were tested?

8. Is the technology effective against non-enveloped respiratory viruses?

Shelf Life and Stability:

9. What is the shelf life and stability of the antimicrobial in this device.

10. Does the device show a failed cytotoxicity score throughout the claimed shelf life.

Leaching Kinetics:

11. What is the rate of elution of antimicrobial in the device.

Biocompatibility Status:

12. Have you evaluated the biocompatibility status of this device.

13. Please provide a complete list of the materials used and the formulation in the final device, including all chemical additives.

14. Please clarify if the device involves any nanoparticles or nano-technologies

Guidance on Surgical Masks: https://www.fda.gov/media/71660/download

Please send us a draft label of your product for our review and comments.

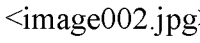
Let me know if you have any questions or concerns.

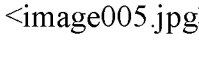
With Respect,
Liz

Elizabeth F. Claverie-Williams, MS
CAPT, USPHS-CC, Microbiologist
Assistant Director, THT4B2: Disinfection, Reprocessing and Personal Protection
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4532 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-6298
Elizabeth.Claverie@fda.hhs.gov

<image001.png>





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From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/19/2020 1:37:31 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; lou.hayden@lowes.com; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Request for expedited FDA action for Hand Sanitizer - Moxie

For sure, Bob.
Mr. Hayden, I am connecting you with my deputy, Dr. Shah.
Best
Steve

Sent from my iPad

On Mar 19, 2020, at 12:44 PM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Steve can you advise who Mr Hayden from Lowe's could connect with th expedite review and approval

Sent from my iPhone

Begin forwarded message:

From: "Hayden, Lou" <lou.hayden@lowes.com>
Date: March 19, 2020 at 12:38:21 PM EDT
To: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Subject: Request for expedited FDA action for Hand Sanitizer - Moxie

Hello Dr. Kadlec – Good to talk with you briefly. During our CEO's call with the President on Tuesday, they asked for contact if we needed help on critical items.

Situation:
We have a found viable source for hand sanitizer out of Mexico and have validated their products. The quickest path to shelf/market is under our Private label Moxie. The vendor brand is registered only in Mexico, not in the US and this registration would take longer. Our Quality Assurance and Legal teams say that it will take 14 - 20 business days for the FDA to assign a labeler code (FDA certification number) and approval of our product label.

Ask:
Is there a contact we can work with at the FDA to expedite this process?

Please let me know how I can help.

Lowe's has 1,750 stores around the U.S. and 300,000 employees, and our products are "essential" for executing social distancing.

With warm regards,

Lou

Lou Hayden
Head of Washington, DC Office
Lowe's Companies
300 New Jersey Avenue NW, Ste. 900
Washington, DC 20001
202-464-2780

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 5:48:13 AM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; 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]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
Subject: Re: COVID-19 Task Force Briefing and Chloroquine Phosphate and Hydroxychloroquine Sulphate

Brett,
Thank you. This is great news.
Anand, is working with an inter-agency work group to organize the supply and supply chain of this drug so that it can be offered off label or on a large pragmatic clinical trial. Additional supply would be very helpful. Anand, would you take this from here?
Thanks
S

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 19, 2020 at 6:03:02 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>
Subject: FW: COVID-19 Task Force Briefing and Chloroquine Phosphate and Hydroxychloroquine Sulphate

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 5:46:20 AM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: (b) (6) Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: FDA Questions for your consideration re: Facemask

Thanks, Bob. I reached out to Jeff when you let me know about this. At that time, we had not received a request for EUA. Jeff, are you able to respond to the question?
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: March 19, 2020 at 6:22:38 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: (b) (6)
Subject: FW: FDA Questions for your consideration re: Facemask

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/3/2020 2:39:39 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]

Subject: HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts
Location: Thomas P. O'Neill Federal Building - 200 C Street SW | Washington, DC 20515

Start: 3/4/2020 9:00:00 AM
End: 3/4/2020 10:15:00 AM
Show Time As: Tentative

Recurrence: (none)

REMINDER: It is requested that you attend in person.
If you are unable to do so, please participate via the dial-in information below:
Number: 202-774-2300
Access Code: 993 881 064

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to ASPR.HCSRTF@hhs.gov no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec
ASPR

POC:
Cicely L. Waters
Director, Office of External Affairs
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 C St, SW Washington, D.C. 20201
(o) 202-205-0714 (m) 202-590-8299
cicely.waters@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith [redacted]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly

Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]

Attachments: COVID-19 Departmental Action Group Agenda 20.03.18.pdf; COVID-19 Departmental Action Group Meeting Notes 20.03.04.pdf
Location: 301-715-8592,,,(b) (6)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

301-715-8592(b) (6)
Join Zoom Meeting
https://zoom.us/(b) (6)
Meeting ID: (b) (6)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

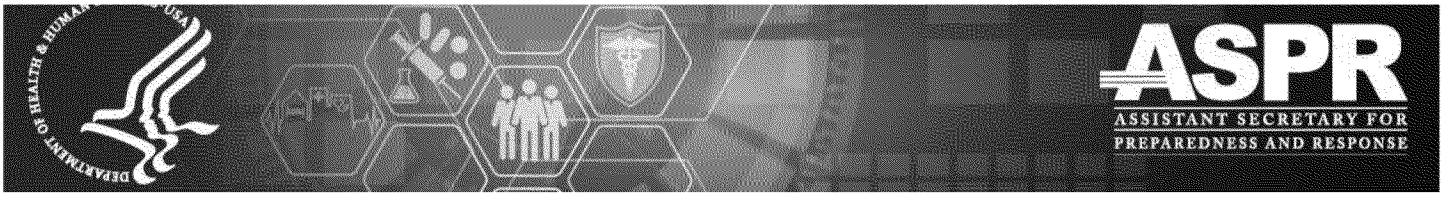
ASPR POC: Jack.herrmann@hhs.gov

U.S. Department of Health and Human Services
COVID-19 Departmental Action Group
Wednesday, March 18, 2020

Zoom meeting: https://zoom.us/j/(b) (6)
Meeting ID: (b) (6)
301-715-8592 [redacted]

Agenda

2:15 pm – 2:30 pm	**Join Zoom meeting**
2:30 pm – 2:35 pm	**Session Kick-Off** Facilitator Jack Herrmann Health Care System Resilience Task Force, ASPR
2:35 pm – 2:45 pm	**ASPR Opening Remarks** Kevin Yeskey, MD Principal Deputy Assistant Secretary, ASPR **CDC Opening Remarks** Nancy Messonnier, MD Director of the National Center for Immunization and Respiratory Diseases, CDC
2:45 pm – 3:30 pm	**HHS Intra-Agency Discussion** • Top Priorities • Key Activities • Operational Challenges • Support Needs
3:30 pm – 3:40 pm	**Summary & Next Steps**
3:40 pm – 3:45 pm	**Closing Remarks**



COVID-19 Health Care System Resilience: Alignment of HHS Efforts (COVID-19 Departmental Action Group)

Summarized Notes (not direct quotes)

Wednesday, March 4, 2020 | 9:00am-10:15am
Thomas P. O'Neill Federal Building | 200 C Street SW | Washington, DC 20515

Session Kick-Off

Jack Herrmann, Health Care System Resilience Task Force (HCSRTF) Lead and Acting Director of the National Healthcare Preparedness Programs, Office of the Assistant Secretary for Preparedness and Response (ASPR)

- The purpose of this meeting is to align U.S. Department of Health and Human Services (HHS) toward one shared approach for driving health care system resiliency – for patients, the health care workforce, and the public – during this COVID-19 response. Our objective for this meeting is to bring leaders from across HHS together to highlight priority areas OPDIVs and STAFFDIVs are working on regarding COVID-19, near term and projected challenges, and what ASPR or other HHS components can do in regarding their missions.

ASPR Opening Remarks

Bryan Shuy, Deputy Assistant Secretary and Chief of Staff for the ASPR

- HHS alignment must happen and it is critical that this is a "one team, one fight" effort. Everyone's involvement is important, and we need to maintain open lines of communication to make it work. We need to know the gaps, issues, and to be able to work together.

Dr. Kevin Yeskey, Principal Deputy Assistant Secretary, ASPR

- In Friday's Disaster Leadership Group meeting, we set the stage from the HHS side to think about mitigation. Things have changed since then as we've seen increased cases and deaths. We are still looking at containment, but there is a need for community mitigation. We need to identify vulnerable populations to have the greatest impact, and focus on individuals with other co-morbidities. ASPR is looking at the whole of HHS response – how we're reaching out to public and private partners to work to the same ends to save the lives of people impacted, and protect and shield the vulnerable from the virus. In this discussion today, we want to hear your priorities, your challenges, and how you'll work with partners to do this on an accelerated timeline.

CDC Opening Remarks

Dr. Nancy Messonnier, Director of the National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention (CDC)

- This situation is full of complexities. The need for speed is urgent and it will take all of government to respond. CDC is supporting implementation and guidance locally and has four main objectives in working with partners:
    1. **Timely and optimal care for COVID-19 patients** (updated guidance)
    2. **Providing care for non- COVID-19 patients** (already proving to be difficult in places like Seattle and throughout Washington; rolling out telehealth tools)
    3. In this situation, the disease in younger kids is relatively mild, so we are focusing on **vulnerable populations** including older adults. We are working on these issues with CMS and geriatric representatives.
    4. **Protecting health care staff** - In California, staff are especially at-risk and because of their potential exposure, might need to be quarantined. An all-government approach is needed.

HHS Intra-Agency Report-Outs

Jack Herrmann, HCSRTF/HPP, ASPR

- ASPR stood up 6 COVID-19 Task Forces to focus on Medical Counter Measures, Supply Chain, Communications, Repatriation, Incident Management, and Health Care System Resilience. The Health Care System Resilience Task Force is facilitating public-private sector collaboration to support ongoing response and mitigation efforts nationwide, and working to establish and maintain a common operating picture of health care system resilience, providing actionable decision support products to federal leaders and private sector partners. The work you shared ahead of time and what we discuss will help inform the ongoing work of that particular task force.

The following summarizes the top priorities and challenges identified by HHS leaders:

Administration for Children and Families (ACF)

- Top priority:
    - Focusing on funding provided to Head Start, Unaccompanied Minors, Family and Youth Services Bureau, and emphasizing guidance to Head Start to communicate that recipients will not be penalized for not meeting certain standards.
    - Leading repatriation and collaborating with ASPR; aligning with any other group providing grantee flexibility guidance.
- Challenge:
    - Protecting workers.

Administration for Community Living (ACL)

- Top Priority:
    - Focusing on the aging population and individuals with disabilities, especially those with upper respiratory problems.
    - Working with CDC to ensure accuracy of communications and disaster recovery documents.
    - Getting guidance for grantees.

Agency for Healthcare Research and Quality (AHRQ)

- Top Priority:
    - Focusing on how to operationalize guidance for primary care.
    - Using data sources to help with modeling bed capacity and surge capacity.
    - Standing ready to support others as needed.
- Challenge:
    - Limited funding.

Food and Drug Administration (FDA)

- Top Priority:
    - Planning CONOPS and workforce management.
    - Identifying ways to support and update HHS STAFFDIVs and OPDIVs.
    - Providing supply chain shortage updates from product centers and assessing diagnostic status.
    - Reviewing preview submissions and staying abreast of clinical trials.
    - Coordinating with HHS on decisions regarding international travel, domestic travel meetings, and widely attended gatherings.

- Ensuring workforce safety.

Health Resources and Services Administration (HRSA)

- Top Priority:
  - Ensuring clinicians have the information they need and guiding them to review CDC's website for the latest guidance.
- Challenge:
  - Preserving the health care system; informing the public about accessing care whether they are potential COVID-19 patients or not.

Indian Health Services (IHS)

- Top Priority:
  - Reaching all members served on community preparedness and mitigation.
- Challenge:
  - Surveillance; visibility into whether a patient has tested positive.
  - Continuing operations and concern about returning officers exposing the community to the virus.

National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID)

- Top Priority:
  - Working closely with FDA and NIH on testing leading therapeutics.
  - Thinking across institutes on modeling.

Substance Abuse and Mental Health Services Administration (SAMHSA)

- Top Priority:
  - Focusing on behavioral health for vulnerable populations.
  - Preparing U.S. health care facilities for behavioral health needs.

Centers for Medicare and Medicaid Services (CMS)

- Top Priority:
  - Focusing on availability of PPE for health care workforce, reviewing pandemic plans, and workplace safety.
  - Working with FDA to understand guidance.
  - Ensuring a billing code is in place for lab developed tests.
  - Developing infection control and PPE guidance that goes to health care facilities, health care workforces, and surveyors.
  - Developing documents to clarify reimbursement for COVID-19 related services.
- Challenge:
  - Availability of PPE for health care workforce.

Centers for Disease Control and Prevention (CDC)

- Top Priority:
  - Providing timely and optimal care for COVID-19 patients, providing care for non-COVID-19 patients, focusing on vulnerable populations, and protecting health care staff.
  - Ensuring that there is available guidance focused on decision support, home care guidance, and infection control throughout entire system, including pharmacies, clinician offices, inpatient care, and scoping

outpatient as well as, ER settings, long-term care, and nursing.
    - Leveraging private sector coordination and task force platforms to coordinate messages going forward.
    - Learning from Washington and California to inform guidance.
- Challenge:
    - Supply chain; ensuring feasibility of recommendations.

HHS Assistant Secretary for Administration (ASA)

- Top Priority:
    - Testing infrastructure, protecting/stress testing email capabilities in case there is a need for telehealth.
    - Preparing for how to provide support if there's trouble accessing the network.
    - Monitoring phishing emails; sharing across the community if this happens.
    - Working with state and local partners to identify cyber attacks that might disrupt access to records and care.
    - Establishing a working group with the technology community across HHS so everyone is aware of the threat and how to protect and operate systems.
- Challenge:
    - Internal and external communications.

Assistant Secretary for Financial Resources (ASFR)

- Top Priority:
    - Informing employees of guidance; sharing OPM guidance.
    - Establishing direct hire authorities.
- Challenge:
    - Triaging questions.

Assistant Secretary for Legislation (ASL)

- Top Priority:
    - Meeting mission essential functions such as communication with legislative branch, congressional hearings, and budget hearings.

Assistant Secretary for Planning and Evaluation (ASPE)

- Top Priority:
    - Completing short-term quick analysis and research for the whole department, and providing information as needed to STAFFDIVs.
    - Answering data calls and standing ready to help.

Office of Intergovernmental and External Affairs (IEA)

- Top Priority:
    - Focusing on private sector outreach, primarily interfacing with governors, state, and local officials.
    - Troubleshooting with White House affairs; organizing a call with providers.
    - Focusing on vulnerable populations, specifically older adults; categorizing CDC materials related to cohorts (e.g., all materials that relate to vulnerable populations).
    - Increasing visibility into documents that ASPA has for HHS and for all other agencies .
- Challenge:

- Meeting internal and external speaker needs.
- Tracking various provider calls.

Office of Pandemics and Global Threats, Office of Global Affairs (OGA)

- Top Priority:
  - Monitoring situation overseas and domestically, which informs conversations with ministries of health.
  - Supporting the Secretary with weekly G7 meetings and conversations with WHO about topics including preparedness, travel advisories, sample sharing, PPE issues, and engaging in conversations with all affected countries.
  - Setting up a DC diplomatic corps meeting.

Office of the Assistant Secretary for Health (OASH)

- Top Priority:
  - Containment: deployed 600 officers to help with repatriation.
  - Mitigation: setting up Clinical Strike Teams to help with specialty providers.
- Challenge:
  - Consistent pre- and post-deployment guidance.

Office of Civil Rights (OCR)

- Top Priority:
  - Translating guidance for individuals with Limited English Proficiency.
  - Suspending elements of HIPAA during an emergency to enable sharing information on people who are disabled or who have comorbidity issues.
  - Preparing local governments to adequately respond to individuals with disabilities.
  - Mitigating violence and bullying.

Office of Medicare Hearings and Appeals (OMHA)

- Comments: We have 10 offices. Telework flexibility and guidance will be important. We are concerned about non-essential domestic travel. We want to hear about our departmental response. We can help to answer questions.
- Offer: With ASA, we've had a conversation about capacities for hiring. We also have staff with medical backgrounds who may be able to be detailed.

National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT)

- Top Priority:
  - Focusing on daily EMS activities nation-wide; transitioning to large event or disaster response.
  - Holding regular conference calls with national EMS organizations (public and private sector, fire service) and state EMS directors; exploring alternative response configurations depending on level of acuity of the caller.
  - Continuing to interface with health care systems and staying consistent with what ASPR is doing.
- Challenge:
  - Staff and workers' safety on field and in office; PPE.

Closing Remarks

Jack Herrmann, HCSRTF/HPP, ASPR

- Asking the question, "What keeps you up at night?" brings out important information. Consider using this with your own members to understand where they are. We can begin to prioritize areas to keep us directed. In the context of this fast-moving response, it will be important to maintain communication. Every day, we have competing priorities.

The challenge is to step back and strategize. Meetings like this are critical to help us hear what's happening, where our priorities are, and where we need help. HHS needs to work together.

Office of External Affairs (OEA), ASPR

- Addressing overall communications efforts has a dedicated Task Force in the response. We are focusing on congressional affairs efforts. We supported the Listening Session earlier this week. We are also focusing on supply chain issues, health care workers, and how to communicate with the general public.

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) (b) (6) Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6)]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]

Location: 301-715-8592, (b) (6)

Start: 3/18/2020 2:30:00 PM

End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

301-715-8592; (b) (6)
Join Zoom Meeting
https://zoom.us/j/ (b) (6)
Meeting ID: (b) (6)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

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Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

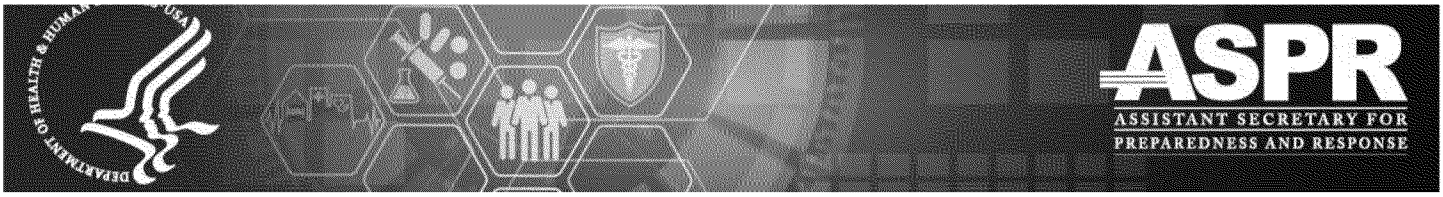
ASPR POC: Jack.herrmann@hhs.gov

U.S. Department of Health and Human Services
COVID-19 Departmental Action Group
Wednesday, March 18, 2020

Zoom meeting: https://zoom.us/j/9[redacted]
Meeting ID: [redacted] Consult wi h HHS
301-715-8592(b) (6) [redacted]

Agenda

2:15 pm – 2:30 pm	**Join Zoom meeting**
2:30 pm – 2:35 pm	**Session Kick-Off** Facilitator Jack Herrmann Health Care System Resilience Task Force, ASPR
2:35 pm – 2:45 pm	**ASPR Opening Remarks** Kevin Yeskey, MD Principal Deputy Assistant Secretary, ASPR **CDC Opening Remarks** Nancy Messonnier, MD Director of the National Center for Immunization and Respiratory Diseases, CDC
2:45 pm – 3:30 pm	**HHS Intra-Agency Discussion** • Top Priorities • Key Activities • Operational Challenges • Support Needs
3:30 pm – 3:40 pm	**Summary & Next Steps**
3:40 pm – 3:45 pm	**Closing Remarks**



COVID-19 Health Care System Resilience: Alignment of HHS Efforts (COVID-19 Departmental Action Group)

Summarized Notes (not direct quotes)

Wednesday, March 4, 2020 | 9:00am-10:15am
Thomas P. O'Neill Federal Building | 200 C Street SW | Washington, DC 20515

Session Kick-Off

Jack Herrmann, Health Care System Resilience Task Force (HCSRTF) Lead and Acting Director of the National Healthcare Preparedness Programs, Office of the Assistant Secretary for Preparedness and Response (ASPR)

- The purpose of this meeting is to align U.S. Department of Health and Human Services (HHS) toward one shared approach for driving health care system resiliency – for patients, the health care workforce, and the public – during this COVID-19 response. Our objective for this meeting is to bring leaders from across HHS together to highlight priority areas OPDIVs and STAFFDIVs are working on regarding COVID-19, near term and projected challenges, and what ASPR or other HHS components can do in regarding their missions.

ASPR Opening Remarks

Bryan Shuy, Deputy Assistant Secretary and Chief of Staff for the ASPR

- HHS alignment must happen and it is critical that this is a "one team, one fight" effort. Everyone's involvement is important, and we need to maintain open lines of communication to make it work. We need to know the gaps, issues, and to be able to work together.

Dr. Kevin Yeskey, Principal Deputy Assistant Secretary, ASPR

- In Friday's Disaster Leadership Group meeting, we set the stage from the HHS side to think about mitigation. Things have changed since then as we've seen increased cases and deaths. We are still looking at containment, but there is a need for community mitigation. We need to identify vulnerable populations to have the greatest impact, and focus on individuals with other co-morbidities. ASPR is looking at the whole of HHS response – how we're reaching out to public and private partners to work to the same ends to save the lives of people impacted, and protect and shield the vulnerable from the virus. In this discussion today, we want to hear your priorities, your challenges, and how you'll work with partners to do this on an accelerated timeline.

CDC Opening Remarks

Dr. Nancy Messonnier, Director of the National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention (CDC)

- This situation is full of complexities. The need for speed is urgent and it will take all of government to respond. CDC is supporting implementation and guidance locally and has four main objectives in working with partners:
    1. **Timely and optimal care for COVID-19 patients** (updated guidance)
    2. **Providing care for non- COVID-19 patients** (already proving to be difficult in places like Seattle and throughout Washington; rolling out telehealth tools)
    3. In this situation, the disease in younger kids is relatively mild, so we are focusing on **vulnerable populations** including older adults. We are working on these issues with CMS and geriatric representatives.
    4. **Protecting health care staff** - In California, staff are especially at-risk and because of their potential exposure, might need to be quarantined. An all-government approach is needed.

HHS Intra-Agency Report-Outs

Jack Herrmann, HCSRTF/HPP, ASPR

- ASPR stood up 6 COVID-19 Task Forces to focus on Medical Counter Measures, Supply Chain, Communications, Repatriation, Incident Management, and Health Care System Resilience. The Health Care System Resilience Task Force is facilitating public-private sector collaboration to support ongoing response and mitigation efforts nationwide, and working to establish and maintain a common operating picture of health care system resilience, providing actionable decision support products to federal leaders and private sector partners. The work you shared ahead of time and what we discuss will help inform the ongoing work of that particular task force.

The following summarizes the top priorities and challenges identified by HHS leaders:

Administration for Children and Families (ACF)

- Top priority:
    - Focusing on funding provided to Head Start, Unaccompanied Minors, Family and Youth Services Bureau, and emphasizing guidance to Head Start to communicate that recipients will not be penalized for not meeting certain standards.
    - Leading repatriation and collaborating with ASPR; aligning with any other group providing grantee flexibility guidance.
- Challenge:
    - Protecting workers.

Administration for Community Living (ACL)

- Top Priority:
    - Focusing on the aging population and individuals with disabilities, especially those with upper respiratory problems.
    - Working with CDC to ensure accuracy of communications and disaster recovery documents.
    - Getting guidance for grantees.

Agency for Healthcare Research and Quality (AHRQ)

- Top Priority:
    - Focusing on how to operationalize guidance for primary care.
    - Using data sources to help with modeling bed capacity and surge capacity.
    - Standing ready to support others as needed.
- Challenge:
    - Limited funding.

Food and Drug Administration (FDA)

- Top Priority:
    - Planning CONOPS and workforce management.
    - Identifying ways to support and update HHS STAFFDIVs and OPDIVs.
    - Providing supply chain shortage updates from product centers and assessing diagnostic status.
    - Reviewing preview submissions and staying abreast of clinical trials.
    - Coordinating with HHS on decisions regarding international travel, domestic travel meetings, and widely attended gatherings.

- Ensuring workforce safety.

Health Resources and Services Administration (HRSA)

- Top Priority:
  - Ensuring clinicians have the information they need and guiding them to review CDC's website for the latest guidance.
- Challenge:
  - Preserving the health care system; informing the public about accessing care whether they are potential COVID-19 patients or not.

Indian Health Services (IHS)

- Top Priority:
  - Reaching all members served on community preparedness and mitigation.
- Challenge:
  - Surveillance; visibility into whether a patient has tested positive.
  - Continuing operations and concern about returning officers exposing the community to the virus.

National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID)

- Top Priority:
  - Working closely with FDA and NIH on testing leading therapeutics.
  - Thinking across institutes on modeling.

Substance Abuse and Mental Health Services Administration (SAMHSA)

- Top Priority:
  - Focusing on behavioral health for vulnerable populations.
  - Preparing U.S. health care facilities for behavioral health needs.

Centers for Medicare and Medicaid Services (CMS)

- Top Priority:
  - Focusing on availability of PPE for health care workforce, reviewing pandemic plans, and workplace safety.
  - Working with FDA to understand guidance.
  - Ensuring a billing code is in place for lab developed tests.
  - Developing infection control and PPE guidance that goes to health care facilities, health care workforces, and surveyors.
  - Developing documents to clarify reimbursement for COVID-19 related services.
- Challenge:
  - Availability of PPE for health care workforce.

Centers for Disease Control and Prevention (CDC)

- Top Priority:
  - Providing timely and optimal care for COVID-19 patients, providing care for non-COVID-19 patients, focusing on vulnerable populations, and protecting health care staff.
  - Ensuring that there is available guidance focused on decision support, home care guidance, and infection control throughout entire system, including pharmacies, clinician offices, inpatient care, and scoping

outpatient as well as, ER settings, long-term care, and nursing.
    - Leveraging private sector coordination and task force platforms to coordinate messages going forward.
    - Learning from Washington and California to inform guidance.
- Challenge:
    - Supply chain; ensuring feasibility of recommendations.

HHS Assistant Secretary for Administration (ASA)

- Top Priority:
    - Testing infrastructure, protecting/stress testing email capabilities in case there is a need for telehealth.
    - Preparing for how to provide support if there's trouble accessing the network.
    - Monitoring phishing emails; sharing across the community if this happens.
    - Working with state and local partners to identify cyber attacks that might disrupt access to records and care.
    - Establishing a working group with the technology community across HHS so everyone is aware of the threat and how to protect and operate systems.
- Challenge:
    - Internal and external communications.

Assistant Secretary for Financial Resources (ASFR)

- Top Priority:
    - Informing employees of guidance; sharing OPM guidance.
    - Establishing direct hire authorities.
- Challenge:
    - Triaging questions.

Assistant Secretary for Legislation (ASL)

- Top Priority:
    - Meeting mission essential functions such as communication with legislative branch, congressional hearings, and budget hearings.

Assistant Secretary for Planning and Evaluation (ASPE)

- Top Priority:
    - Completing short-term quick analysis and research for the whole department, and providing information as needed to STAFFDIVs.
    - Answering data calls and standing ready to help.

Office of Intergovernmental and External Affairs (IEA)

- Top Priority:
    - Focusing on private sector outreach, primarily interfacing with governors, state, and local officials.
    - Troubleshooting with White House affairs; organizing a call with providers.
    - Focusing on vulnerable populations, specifically older adults; categorizing CDC materials related to cohorts (e.g., all materials that relate to vulnerable populations).
    - Increasing visibility into documents that ASPA has for HHS and for all other agencies .
- Challenge:

- Meeting internal and external speaker needs.
- Tracking various provider calls.

Office of Pandemics and Global Threats, Office of Global Affairs (OGA)

- Top Priority:
  - Monitoring situation overseas and domestically, which informs conversations with ministries of health.
  - Supporting the Secretary with weekly G7 meetings and conversations with WHO about topics including preparedness, travel advisories, sample sharing, PPE issues, and engaging in conversations with all affected countries.
  - Setting up a DC diplomatic corps meeting.

Office of the Assistant Secretary for Health (OASH)

- Top Priority:
  - Containment: deployed 600 officers to help with repatriation.
  - Mitigation: setting up Clinical Strike Teams to help with specialty providers.
- Challenge:
  - Consistent pre- and post-deployment guidance.

Office of Civil Rights (OCR)

- Top Priority:
  - Translating guidance for individuals with Limited English Proficiency.
  - Suspending elements of HIPAA during an emergency to enable sharing information on people who are disabled or who have comorbidity issues.
  - Preparing local governments to adequately respond to individuals with disabilities.
  - Mitigating violence and bullying.

Office of Medicare Hearings and Appeals (OMHA)

- Comments: We have 10 offices. Telework flexibility and guidance will be important. We are concerned about non-essential domestic travel. We want to hear about our departmental response. We can help to answer questions.
- Offer: With ASA, we've had a conversation about capacities for hiring. We also have staff with medical backgrounds who may be able to be detailed.

National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT)

- Top Priority:
  - Focusing on daily EMS activities nation-wide; transitioning to large event or disaster response.
  - Holding regular conference calls with national EMS organizations (public and private sector, fire service) and state EMS directors; exploring alternative response configurations depending on level of acuity of the caller.
  - Continuing to interface with health care systems and staying consistent with what ASPR is doing.
- Challenge:
  - Staff and workers' safety on field and in office; PPE.

Closing Remarks

Jack Herrmann, HCSRTF/HPP, ASPR

- Asking the question, "What keeps you up at night?" brings out important information. Consider using this with your own members to understand where they are. We can begin to prioritize areas to keep us directed. In the context of this fast-moving response, it will be important to maintain communication. Every day, we have competing priorities.

The challenge is to step back and strategize. Meetings like this are critical to help us hear what's happening, where our priorities are, and where we need help. HHS needs to work together.

Office of External Affairs (OEA), ASPR

- Addressing overall communications efforts has a dedicated Task Force in the response. We are focusing on congressional affairs efforts. We supported the Listening Session earlier this week. We are also focusing on supply chain issues, health care workers, and how to communicate with the general public.

To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (b) (6) Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

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Attachments: COVID-19 Departmental Action Group Agenda 20.03.18.pdf; COVID-19 Departmental Action Group Meeting Notes 20.03.04.pdf

Location: 301-715-8592, (b) (6)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

301-715-8592; (b) (6)
Join Zoom Meeting
https://zoom.us/ (b) (6)
Meeting ID: (b) (6)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith [redacted]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly

Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]

Location: 301-715-8592,,,942013302#

Start: 3/18/2020 2:30:00 PM

End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

301-715-8592; (b) (6)
Join Zoom Meeting
https://zoom.us/ (b) (6)
Meeting ID: (b) (6)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore

(SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith

(uscg.mil) [Meredith.L.Austin@uscg.mil]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore

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Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM

Show Time As: Tentative

Recurrence: (none)

301-715-8592 (b) (6)
Join Zoom Meeting
https://zoom.us/ (b) (6)
Meeting ID: (b) (6)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore

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Subject: COVID-19 Departmental Action Group
Attachments: Untitled Attachment
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]; Rothschild, Feride (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd3b886dd357420a9086fce473261a8d-HHS-Feride.]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; White, Summer [sumwhite@deloitte.com]; Braunstein, Sofia [sobraunstein@deloitte.com]

Location: 301-715-8592,,,942013302#

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: (none)

301-715-8592; (b) (6)
Join Zoom Meeting
https://zoom.us (b) (6)
Meeting ID: (b) (6)

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 3/16/2020 5:59:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; 'Op Divs' [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore

(SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Stevens, Lee R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=183b49fc951b40d1bab6fbee680803d5-HHS-Lee.Ste]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Bratcher-Bowman, Nikki (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ffd3917e74a42bea897beab6413d626-HHS-nikki.b]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Allen, Ronald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66121d59d5ff4b19a44429dd7c3d66ff-HHS-Ronald.]; Marlowe, Amelia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb42265c0d9a4f1e8224487469e61f38-HHS-Amelia.]; Islam, Ahmed (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e147cb8d9a374f1682a146ae5589615f-HHS-Ahmed.I]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Thompson, Donna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=641b42d4d0234c41b75bb7d5c5f4ae9f-HHS-Donna.T]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Austin, Meredith

(uscg.mil) [Meredith.L.Austin@uscg.mil]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Williams, Rasheed (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3865e837ab01414c8580b9c573d9cfa8-HHS-Rasheed]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kilbourn Shear, Emily C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=820cd330255544cb90441c43f461464f-HHS-nfo2-cd]

Subject: COVID-19 Departmental Action Group
Location: TBA (Teleconfernece Information forthcoming)

Start: 3/18/2020 2:30:00 PM
End: 3/18/2020 3:45:00 PM
Show Time As: Tentative

Recurrence: Weekly
Occurs on Wednesday every other week from 2:30 PM to 3:45 PM effective 3/18/2020.

Meeting Purpose: To provide an ongoing operational and information sharing venue across the Department during the COVID-19 response, focusing on near term priorities, activities, challenges, and support needs.

Meeting Time: Every other Wednesday (2:30-3:45 pm EDT)

Standing Agenda:

- Kickoff
- ASPR Opening Remarks
- CDC Opening Remarks
- HHS Intra-Agency Updates
- Top Priorities
- Key Activities
- Operational Challenges
- Support Needs
- Summary and Next Steps
- Closing

ASPR POC: Jack.herrmann@hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/18/2020 3:25:28 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC (b) (6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

We can certainly work with them. Does anyone know any of these folks?

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Date: April 18, 2020 at 10:51:33 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:

Thanks for the quick reply. The data from the Stanford group have extremely important implications for how we view the scope and dynamics of the outbreak. Is there any way that you can have FDA work with them so that FDA can validate their assay? I feel that it is important that you do this given the implications of these data.

Thanks,

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
(b) (6)
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From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, April 18, 2020 10:31 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6) >
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Tony,
We have not authorized a lateral flow test yet for use as described. We have a significant number of serology tests under review and NCI is still validating some of the others.

We are working with a lot of laboratories and manufacturers and take our responsibilities in this area very seriously. We are very happy to work with all parties and have, in fact, done so. I have a regular call with the American Public Health Laboratory leadership and have offered to work closely on the tests that they and their stakeholders are using. I also have a regular call (weekly of late) with lab test manufacturers to discuss progress and attempt to remove any roadblocks.

Yesterday, we posted new FAQs and additional communications regarding the tests that have been authorized as well as our efforts with NCI to provide additional transparency to the validation data. Those communications also encourage engagement with FDA.

I am open to your suggestions on how we can further engage with parties who are doing testing of which we are unaware. I think the team on this email string could also continue to message that if a group is using a test not authorized by FDA, they must either engage with us for technical assistance or perform their own validation. Glad to discuss further.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >
Date: April 18, 2020 at 10:03:32 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Subject: FW: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:
Was the antibody test that they used validated by FDA and could they have ben measuring cross-reacting antibodies with benign coronaviruses that subjects had been previously exposed to? It is essential that the FDA work with them to figure this out.
Thanks,
Tony

From: Folkers, Greg (NIH/NIAID) [E] <(b) (6) >
Sent: Friday, April 17, 2020 5:44 PM
Subject: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

COVID-19 Antibody Seroprevalence in Santa Clara County, California

Eran Bendavid, Bianca Mulaney, Neeraj Sood, Soleil Shah, Emilia Ling, Rebecca Bromley-Dulfano, Cara Lai, Zoe Weissberg, Rodrigo Saavedra, James Tedrow, Dona Tversky, Andrew Bogan, Thomas Kupiec, Daniel Eichner, Ribhav Gupta, John Ioannidis, Jay Bhattacharya

doi: https://doi.org[redacted] (b) (6)

- Abstract
- Info/History
- Metrics
- Preview PDF

Abstract

Background Addressing COVID-19 is a pressing health and social concern. To date, many epidemic projections and policies addressing COVID-19 have been designed without seroprevalence data to inform epidemic parameters. We measured the seroprevalence of antibodies to SARS-CoV-2 in Santa Clara County. Methods On 4/3-4/4, 2020, we tested county residents for antibodies to SARS-CoV-2 using a lateral flow immunoassay. Participants were recruited using Facebook ads targeting a representative sample of the county by demographic and geographic characteristics. We report the prevalence of antibodies to SARS-CoV-2 in a sample of 3,330 people, adjusting for zip code, sex, and race/ethnicity. We also adjust for test performance characteristics using 3 different estimates: (i) the test manufacturer's data, (ii) a sample of 37 positive and 30 negative controls tested at Stanford, and (iii) a combination of both. Results The unadjusted prevalence of antibodies to SARS-CoV-2 in Santa Clara County was 1.5% (exact binomial 95CI 1.11-1.97%), and the population-weighted prevalence was 2.81% (95CI 2.24-3.37%). Under the three scenarios for test performance characteristics, the population prevalence of COVID-19 in Santa Clara ranged from 2.49% (95CI 1.80-3.17%) to 4.16% (2.58-5.70%). These prevalence estimates represent a range between 48,000 and 81,000 people infected in Santa Clara County by early April, 50-85-fold more than the number of confirmed cases. Conclusions The population prevalence of SARS-CoV-2 antibodies in Santa Clara County implies that the infection is much more widespread than indicated by the number of confirmed cases. Population prevalence estimates can now be used to calibrate epidemic and mortality projections.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/17/2020 1:26:15 PM
To: Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; [redacted] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Navarro, Peter K. EOP/WHO [Peter.K.Navarro@who.eop.gov]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Sharpless, Norman E (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d860d490594f4675960aad587639ed9c-HHS-norman.]
CC: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)]; Adam Boehler [redacted] (b) (6)
Subject: RE: Rapid Testing -- ANTIBODY TESTING

Validation by NCI is in process.
We are reviewing multiple EUAs from manufacturers including point of care tests. The manufacturers are performing the studies needed for validation and we are working closely and daily with them.
Steve

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: April 16, 2020 at 3:15:39 PM EDT
To: [redacted] (b) (6)>, Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Sharpless, Norman E (NIH) <[redacted] (b) (6)>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: MBX WHO SR ADV FOR POL COVID Action <[redacted] (b) (6)>, Adam Boehler <[redacted] (b) (6)
Subject: RE: Rapid Testing -- ANTIBODY TESTING

Great
They need to be evaluated by FDA/CDC/NCI
Dr Sharpless and Dr Hahn copied

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: [redacted] (b) (6)>
Sent: Tuesday, April 14, 2020 2:42 PM
To: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>; Adam Boehler

[redacted] (b) (6)
Subject: Re: Rapid Testing -- ANTIBODY TESTING

Resending to get ADM Giroir in the loop.

From: [redacted] (b) (6)>
Date: Tuesday, April 14, 2020 at 2:40 PM
To: "Navarro, Peter K. EOP/WHO" <Peter.K.Navarro@who.eop.gov>, Robert Kadlec <Robert.Kadlec@hhs.gov>, Brett Giroir <BGiroir@tpevc.com>, Tammy Beckham <Tammy.Beckham@hhs.gov>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>, Adam Boehler <[redacted] (b) (6)
Subject: Re: Rapid Testing -- ANTIBODY TESTING

Peter,

Looping in ADM Brett Giroir and Tammy Beckham who lead this charge for HHS and the Testing Task Force. They are in process of evaluating dozens of antibody tests.

[redacted] (b) (6)

From: "Navarro, Peter K. EOP/WHO" <Peter.K.Navarro@who.eop.gov>
Date: Tuesday, April 14, 2020 at 2:34 PM
To: Robert Kadlec <Robert.Kadlec@hhs.gov>, '[redacted] (b) (6)>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>, Adam Boehler <[redacted] (b) (6)
Subject: FW: Rapid Testing -- ANTIBODY TESTING

Bob, [redacted] (b) (6),

My shop did a prelim screen of this and they were field tested by CST teams in NY to good reviews. The name of the company is **Premier Biotech**. Website below. They can ship 1.5 million units by Monday and the rest of the 5 million in 4-5 days after.

Made in the USA.

Is it worth getting a proposal from them? They can make 5 million in 10 days and plenty over time.

https://protect2.fireeye.com[redacted] (b) (6)
[redacted]

723 Kasota Avenue SE
Minneapolis, MN 55414

From: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>
Sent: Tuesday, April 14, 2020 9:01 AM
To: McCommas, Brendan N. EOP/WHO <Brendan.N.McCommas@who.eop.gov>
Cc: Miller, Joanna R. EOP/WHO <Joanna.R.Miller3@who.eop.gov>; MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)
Subject: RE: Rapid Testing

Steve, please evaluate please. If good we can move up chain

From: McCommas, Brendan N. EOP/WHO <Brendan.N.McCommas@who.eop.gov>
Sent: Monday, April 13, 2020 7:55 PM
To: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>
Cc: Miller, Joanna R. EOP/WHO <Joanna.R.Miller3@who.eop.gov>; MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)
Subject: Rapid Testing

Hi Dr. Navarro – I just wanted to pass along the attached document describing a test using antibodies for COVID-19.

I have been working with Dr. Hatfill and Joanna to get these rapid tests out and there are 120 with the CST team up in NY to test. The company makes the tests in Minnesota and they can make 5 milion in 10 days. Mexico has already bought 5 million of the tests.

Brendan

Brendan McCommas
Special Assistant to the President
Office of Trade and Manufacturing Policy
(C) 202-881-7449
The President's two simple rules: "Buy American, Hire American."

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/18/2020 6:30:55 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

We'll work on putting it together.
S

From: Fauci, Anthony (NIH/NIAID) [E] [redacted]
Date: April 18, 2020 at 6:21:44 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) [redacted], Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Great idea!

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: (301) 496-4409
E-mail: [redacted]

From: Hahn, Stephen <[redacted]@fda.hhs.gov>
Sent: Saturday, April 18, 2020 6:19 PM

To: Fauci, Anthony (NIH/NIAID) [E] <a(b) (6)
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6); Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Team,
Anand Shah, Deputy Commissioner, reached out to the Stanford investigators on our behalf. Very interesting information regarding their research and the test that they are using. They are interested in partnering with us. I'll let Anand give the details.

Anand will be reaching out to the MGH folks, as well. (b) (5)

Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Date: April 18, 2020 at 3:38:39 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) (b) (6)
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:
John Ioannidis is the one that most of us know. He is the person one of your people could reach out to.
Thanks,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
(b) (6)
National Institutes of Health
Bethesda, MD 20892-2520
Phone: ((b) (6)
FAX: (301) 496-4409
E-mail: a(b) (6)

From: Hahn, Stephen <(b) (6)@fda.hhs.gov>
Sent: Saturday, April 18, 2020 3:25 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6)
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lane, Cliff

(NIH/NIAID) [E] (b) (6)
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

We can certainly work with them. Does anyone know any of these folks?

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Date: April 18, 2020 at 10:51:33 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) <c(b) (6)>
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:
Thanks for the quick reply. The data from the Stanford group have extremely important implications for how we view the scope and dynamics of the outbreak. Is there any way that you can have FDA work with them so that FDA can validate their assay? I feel that it is important that you do this given the implications of these data.
Thanks,
Tony

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Director
National Institute of Allergy and Infectious Diseases
(b) (6)
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National Institutes of Health
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, April 18, 2020 10:31 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Tony,
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Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)
Date: April 18, 2020 at 10:03:32 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Subject: FW: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:
Was the antibody test that they used validated by FDA and could they have ben measuring cross-reacting antibodies with benign coronaviruses that subjects had been previously exposed to? It is essential that the FDA work with them to figure this out.
Thanks,
Tony

From: Folkers, Greg (NIH/NIAID) [E] (b) (6) >
Sent: Friday, April 17, 2020 5:44 PM
Subject: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

COVID-19 Antibody Seroprevalence in Santa Clara County, California

Eran Bendavid, Bianca Mulaney, Neeraj Sood, Soleil Shah, Emilia Ling, Rebecca Bromley-Dulfano, Cara Lai, Zoe Weissberg, Rodrigo Saavedra, James Tedrow, Dona Tversky, Andrew Bogan, Thomas Kupiec, Daniel Eichner, Ribhav Gupta, John Ioannidis, Jay Bhattacharya

doi: https://doi.org/ (b) (6)

- Abstract
- Info/History
- Metrics
- Preview PDF

Abstract
Background Addressing COVID-19 is a pressing health and social concern. To date, many epidemic projections and policies addressing COVID-19 have been designed without seroprevalence data to inform epidemic parameters. We measured the seroprevalence of antibodies to SARS-CoV-2 in Santa Clara County. Methods On 4/3-4/4, 2020, we tested county residents for antibodies to SARS-CoV-2 using a lateral flow immunoassay. Participants were recruited using Facebook ads targeting a representative sample of the county by demographic and geographic characteristics. We report the prevalence of antibodies to SARS-CoV-2 in a sample of 3,330 people, adjusting for zip code, sex, and

race/ethnicity. We also adjust for test performance characteristics using 3 different estimates: (i) the test manufacturer's data, (ii) a sample of 37 positive and 30 negative controls tested at Stanford, and (iii) a combination of both. Results The unadjusted prevalence of antibodies to SARS-CoV-2 in Santa Clara County was 1.5% (exact binomial 95CI 1.11-1.97%), and the population-weighted prevalence was 2.81% (95CI 2.24-3.37%). Under the three scenarios for test performance characteristics, the population prevalence of COVID-19 in Santa Clara ranged from 2.49% (95CI 1.80-3.17%) to 4.16% (2.58-5.70%). These prevalence estimates represent a range between 48,000 and 81,000 people infected in Santa Clara County by early April, 50-85-fold more than the number of confirmed cases. Conclusions The population prevalence of SARS-CoV-2 antibodies in Santa Clara County implies that the infection is much more widespread than indicated by the number of confirmed cases. Population prevalence estimates can now be used to calibrate epidemic and mortality projections.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/18/2020 6:18:49 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [(b) (6)]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Team,
Anand Shah, Deputy Commissioner, reached out to the (b) (4) investigators on our behalf. Very interesting information regarding their research and the test that they are using. They are interested in partnering with us. I'll let Anand give the details.

Anand will be reaching out to the (b) (4) folks, as well. (b) (5)

Steve

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >
Date: April 18, 2020 at 3:38:39 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) <(b) (6) >
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:
John Ioannidis is the one that most of us know. He is the person one of your people could reach out to.
Thanks,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
(b) (6)

Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b)(5)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, April 18, 2020 3:25 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6) >
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Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) (b) (6) >
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Anthony S. Fauci, MD
Director
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Building 31, Room 7A-03
(b) (6)
Bethesda, MD 20892-2520
Phone: (b) (6)
FAX: (301) 496-4409
E-mail: (b) (6)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, April 18, 2020 10:31 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6) [redacted]
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
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Date: April 18, 2020 at 10:03:32 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Subject: FW: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Steve:
Was the antibody test that they used validated by FDA and could they have ben measuring cross-reacting antibodies with benign coronaviruses that subjects had been previously exposed to? It is essential that the FDA work with them to figure this out.
Thanks,
Tony

From: Folkers, Greg (NIH/NIAID) [E] <(b) (6) [redacted]
Sent: Friday, April 17, 2020 5:44 PM
Subject: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

COVID-19 Antibody Seroprevalence in Santa Clara County, California

Eran Bendavid, Bianca Mulaney, Neeraj Sood, Soleil Shah, Emilia Ling, Rebecca Bromley-Dulfano, Cara Lai, Zoe Weissberg, Rodrigo Saavedra, James Tedrow, Dona Tversky, Andrew Bogan, Thomas Kupiec, Daniel Eichner, Ribhav Gupta, John Ioannidis, Jay Bhattacharya

doi: https://doi.org/[redacted] (b) (6)

- Abstract
- Info/History
- Metrics
- Preview PDF

Abstract

Background Addressing COVID-19 is a pressing health and social concern. To date, many epidemic projections and policies addressing COVID-19 have been designed without seroprevalence data to inform epidemic parameters. We measured the seroprevalence of antibodies to SARS-CoV-2 in Santa Clara County. Methods On 4/3-4/4, 2020, we tested county residents for antibodies to SARS-CoV-2 using a lateral flow immunoassay. Participants were recruited using Facebook ads targeting a representative sample of the county by demographic and geographic characteristics. We report the prevalence of antibodies to SARS-CoV-2 in a sample of 3,330 people, adjusting for zip code, sex, and race/ethnicity. We also adjust for test performance characteristics using 3 different estimates: (i) the test manufacturer's data, (ii) a sample of 37 positive and 30 negative controls tested at Stanford, and (iii) a combination of both. Results The unadjusted prevalence of antibodies to SARS-CoV-2 in Santa Clara County was 1.5% (exact binomial 95CI 1.11-1.97%), and the population-weighted prevalence was 2.81% (95CI 2.24-3.37%). Under the three scenarios for test performance characteristics, the population prevalence of COVID-19 in Santa Clara ranged from 2.49% (95CI 1.80-3.17%) to 4.16% (2.58-5.70%). These prevalence estimates represent a range between 48,000 and 81,000 people infected in Santa Clara County by early April, 50-85-fold more than the number of confirmed cases. Conclusions The population prevalence of SARS-CoV-2 antibodies in Santa Clara County implies that the infection is much more widespread than indicated by the number of confirmed cases. Population prevalence estimates can now be used to calibrate epidemic and mortality projections.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/18/2020 10:30:58 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Tony,
We have not authorized a lateral flow test yet for use as described. We have a significant number of serology tests under review and NCI is still validating some of the others.

We are working with a lot of laboratories and manufacturers and take our responsibilities in this area very seriously. We are very happy to work with all parties and have, in fact, done so. I have a regular call with the American Public Health Laboratory leadership and have offered to work closely on the tests that they and their stakeholders are using. I also have a regular call (weekly of late) with lab test manufacturers to discuss progress and attempt to remove any roadblocks.

Yesterday, we posted new FAQs and additional communications regarding the tests that have been authorized as well as our efforts with NCI to provide additional transparency to the validation data. Those communications also encourage engagement with FDA.

I am open to your suggestions on how we can further engage with parties who are doing testing of which we are unaware. I think the team on this email string could also continue to message that if a group is using a test not authorized by FDA, they must either engage with us for technical assistance or perform their own validation. Glad to discuss further.
Steve

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To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Subject: FW: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

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Background Addressing COVID-19 is a pressing health and social concern. To date, many epidemic projections and policies addressing COVID-19 have been designed without seroprevalence data to inform epidemic parameters. We measured the seroprevalence of antibodies to SARS-CoV-2 in Santa Clara County. Methods On 4/3-4/4, 2020, we tested county residents for antibodies to SARS-CoV-2 using a lateral flow immunoassay. Participants were recruited using Facebook ads targeting a representative sample of the county by demographic and geographic characteristics. We report the prevalence of antibodies to SARS-CoV-2 in a sample of 3,330 people, adjusting for zip code, sex, and race/ethnicity. We also adjust for test performance characteristics using 3 different estimates: (i) the test manufacturer's data, (ii) a sample of 37 positive and 30 negative controls tested at Stanford, and (iii) a combination of both. Results The unadjusted prevalence of antibodies to SARS-CoV-2 in Santa Clara County was 1.5% (exact binomial 95CI 1.11-1.97%), and the population-weighted prevalence was 2.81% (95CI 2.24-3.37%). Under the three scenarios for test performance characteristics, the population prevalence of COVID-19 in Santa Clara ranged from 2.49% (95CI 1.80-3.17%) to 4.16% (2.58-5.70%). These prevalence estimates represent a range between 48,000 and 81,000 people infected in Santa Clara County by early April, 50-85-fold more than the number of confirmed cases. Conclusions The population prevalence of SARS-CoV-2 antibodies in Santa Clara County implies that the infection is much more widespread than indicated by the number of confirmed cases. Population prevalence estimates can now be used to calibrate epidemic and mortality projections.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/15/2020 9:37:53 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Belew, Yodit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3498722efcf48e19d2900a772a65413-BELEWY]
CC: Anderson, Michael [Michael.Anderson@ucsf.edu]; Garrett, Andrew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84cf75bfe35243aea04b0c91bc72c9f8-HHS-Andrew.]
Subject: RE: DO you have a POC fro the Peds MIS-CIssue

Sounds good to me

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: May 15, 2020 at 9:37:17 AM EDT
To: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Belew, Yodit <Yodit.Belew@fda.hhs.gov>
Cc: Anderson, Michael <Michael.Anderson@ucsf.edu>, Garrett, Andrew (OS) <Andrew.Garrett@hhs.gov>
Subject: RE: DO you have a POC fro the Peds MIS-CIssue

Sir, we would recommend Dr. Belew. Dr. Belew is a pediatric ID physician in CDER who has been our lead working on pediatric COVID-19 natural history studies.

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Friday, May 15, 2020 8:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Anderson, Michael <Michael.Anderson@ucsf.edu>; Garrett, Andrew (OS) <Andrew.Garrett@hhs.gov>
Subject: RE: DO you have a POC fro the Peds MIS-CIssue

Ooops thank you

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, May 15, 2020 8:14 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>
Cc: Anderson, Michael <Michael.Anderson@ucsf.edu>; Garrett, Andrew (OS/ASPR/EMMO) <Andrew.Garrett@hhs.gov>
Subject: Re: DO you have a POC fro the Peds MIS-CIssue

Adding Steve's correct email.

Sent from my iPhone

On May 15, 2020, at 8:09 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Good morning Steve we are putting together a HHS group looking at the COVID19 syndrome in kids and wondered if you had any one in your agencydesignated to the follow the issue. If you could please share the name and contact info would be much obliged. Best Bob

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/11/2020 7:52:03 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]
Subject: Re: testing, testing, testing

Morning all,
I agree with Tony that it's important for us to have this discussion. A lot of us are getting questions along the lines that Tony describes so it will be important for all of us to have a common understanding. Brett, very much appreciate all of the work that has gone into our testing efforts.
Steve

From: Tony Fauci (b) (6)
Date: Sunday, May 10, 2020 at 8:41 PM
To: Brett Giroir <Brett.Giroir@hhs.gov>, Debi Birx <Deborah.L.Birx@nsc.eop.gov>, Robert Redfield <olx1@cdc.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Jerome Adams <Jerome.Adams@hhs.gov>, Robert Kadlec <Robert.Kadlec@hhs.gov>
Cc: Francis Collins <collinsf@od.nih.gov>
Subject: RE: testing, testing, testing

Brett:
Thanks for the note. I look forward to discussing this with you.
Best regards,
Tony

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Sunday, May 10, 2020 5:00 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b) (6) (b)(5) Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Collins, Francis (NIH/OD) [E] (b) (6) >; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: RE: testing, testing, testing

Tony,

I am really surprised at your email.

- Do you really think we are not planning for asymptomatic testing - did you look at the new prioritization scheme that is explicit about that?

- Did you not hear that we are planning to do 12.9 million tests in May – more per capita in one month than nearly every country has done per capita to date?
- Were you not aware that we have met with every state and territory individually to develop testing plans? And that we continue to work with them through the CDC awards to assure broad testing?
- In terms of Manhattan project, did you miss the $1Billion going to NIH/BARDA to have new tech breakthroughs? Francis is doing that personally
- But do you know – even without the NIH producing something new and practical (which is a good assumption) – that we will easily have 40+ million tests per month (if we need them) by September? That number could easily be >50 million, and perhaps more.

Happy to discuss next time we meet.

BG

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >
Sent: Sunday, May 10, 2020 4:28 PM
To: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: testing, testing, testing

Folks:
The link below is an article by Harold Varmus representing the deliberations of 10 world-class scientists. It emphasizes the recurrent theme that continues to be our vulnerability, i.e. our lack of ability and/or will to do massive testing that goes well beyond just test to identify those that are infected for the purpose of isolation and contact tracing. The article talks about what we have often discussed, i.e. the need for widespread population-based testing for the purpose of assisting us in an adequate approach as we prepare to open the country again. Do we really have a plan to do that? I have not heard that articulated. We talk about a Manhattan project for vaccines and therapeutics. Should we consider a Manhattan project to get enough tests so that we can test anybody and everybody on a regular basis? The argument that a test today that is negative does not mean that you will not get infected and be positive 2 days from now does not really hold very well for the purposes in question. If that were the case, why are we thinking of doing a massive testing of the White House complex to discover the likely asymptomatic carrier (s) who might have infected our colleague? This article is worth a read. Maybe we can discuss it the next time we meet, which might be virtual.

https://www.theatlantic.com/ideas/archive/2020/05/lack-testing-holding-science-back/611422/

Thanks,
Tony

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/18/2020 10:47:27 AM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
CC: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]
Subject: RE: Recommendation for a briefing by Dr. Dan Jernigan concerning Reopening Framework
Attachments: re-opening framework UCG 4-14 (003) (002).pptx

Thank you we weren't sure and wanted to make sure that if you hadn't it would be made available. Please find attached the brief provided to the UCG.

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Saturday, April 18, 2020 10:38 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>
Subject: Re: Recommendation for a briefing by Dr. Dan Jernigan concerning Reopening Framework

I believe we were briefed on this before the guidelines but happy to hear it again.

Sent from my iPhone

On Apr 18, 2020, at 10:32 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

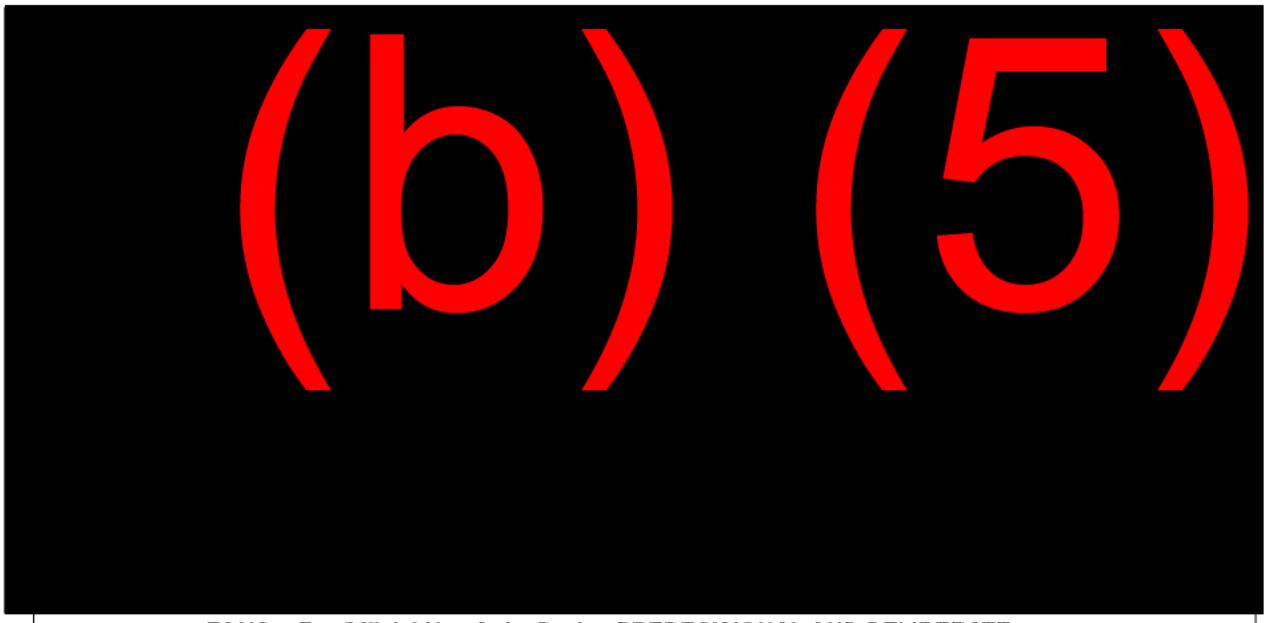
Dr. Jernigan presented a Reopening Framework to the FEMA UCG this week that will be recommended to the WHTF. I would suggest it be previewed by the scientific and clinical membership of the WHTF to preview before recommending it to the broader WHTF membership. We will work to accommodate your collective schedules to arrange. Best Bob

Adjusting Mitigation Strategies – A Framework for Re-Opening

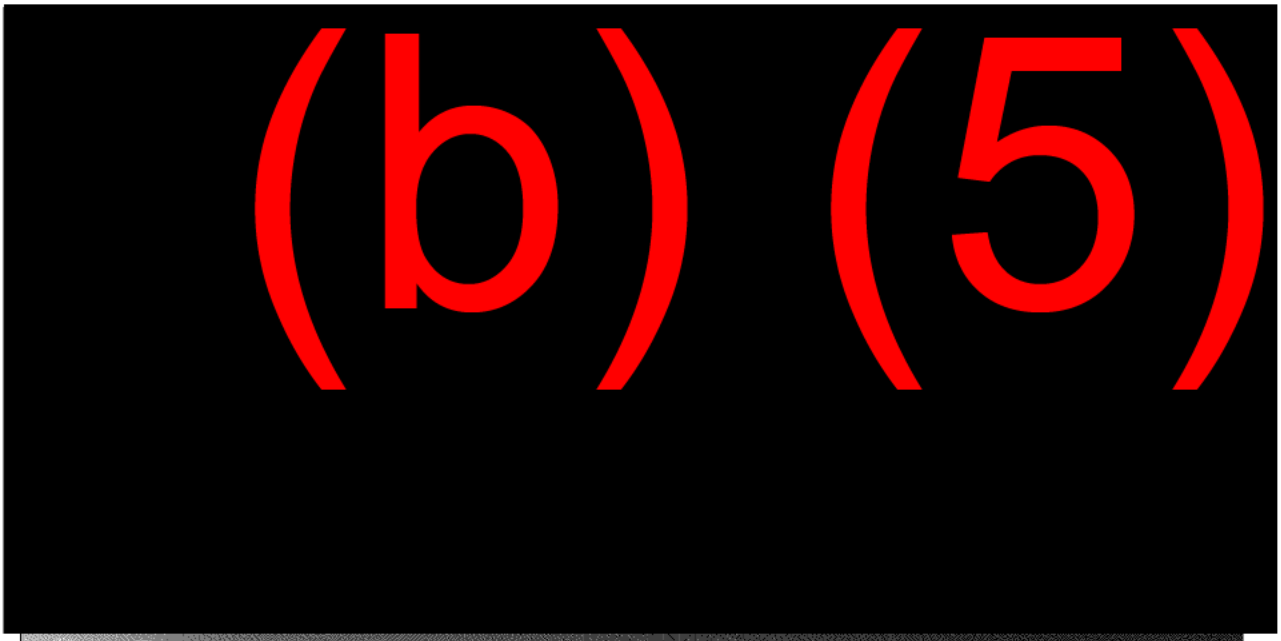
Data & Analytics Task Force and Community Mitigation Task Force

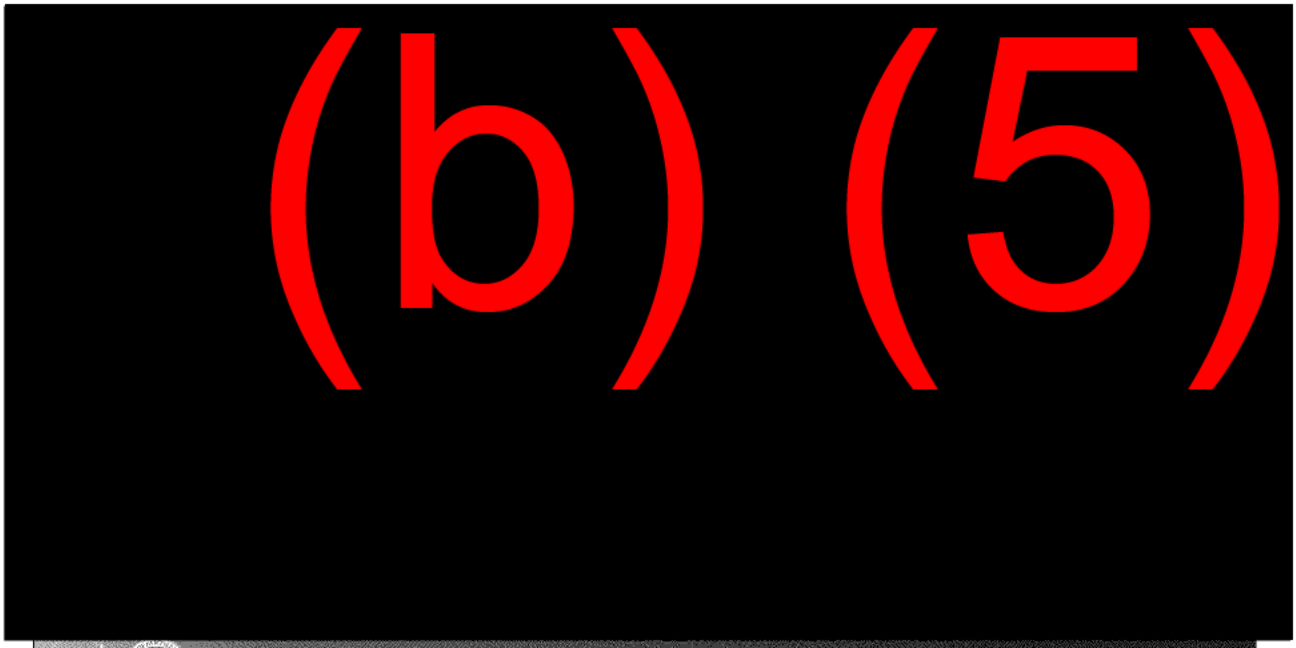
April 14, 2020

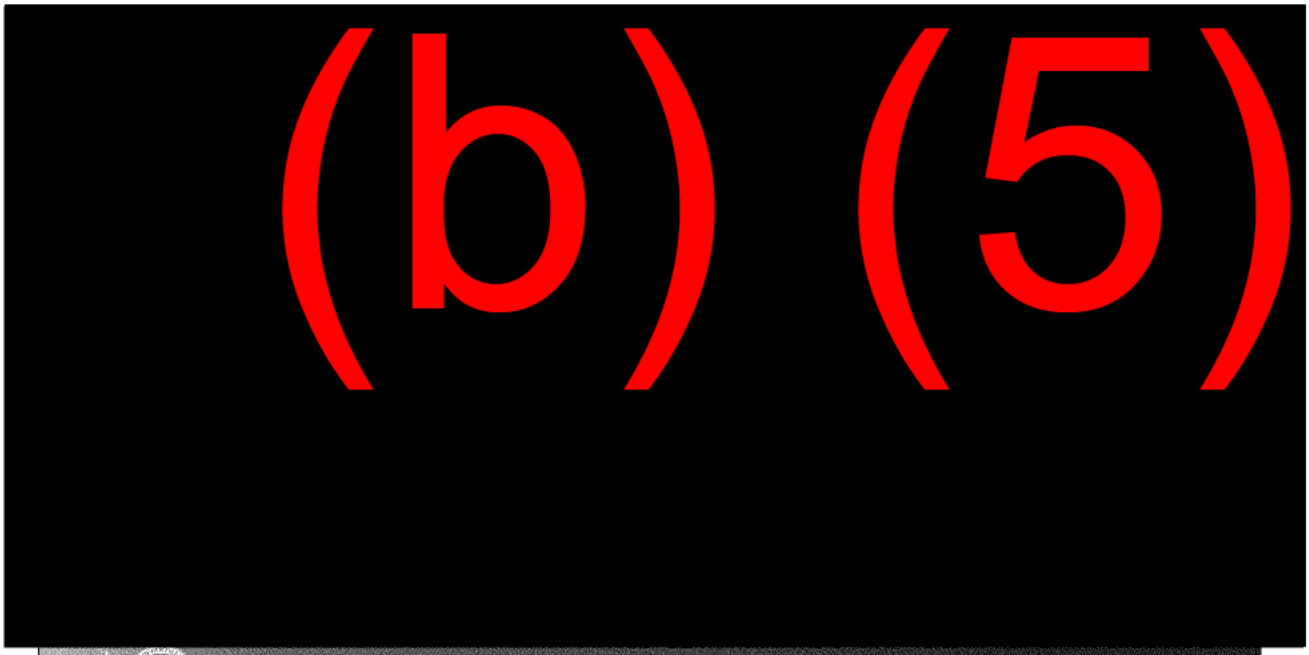
- *FOUO – For Official Use Only .Draft – PREDECISIONAL AND DELIBERATE*

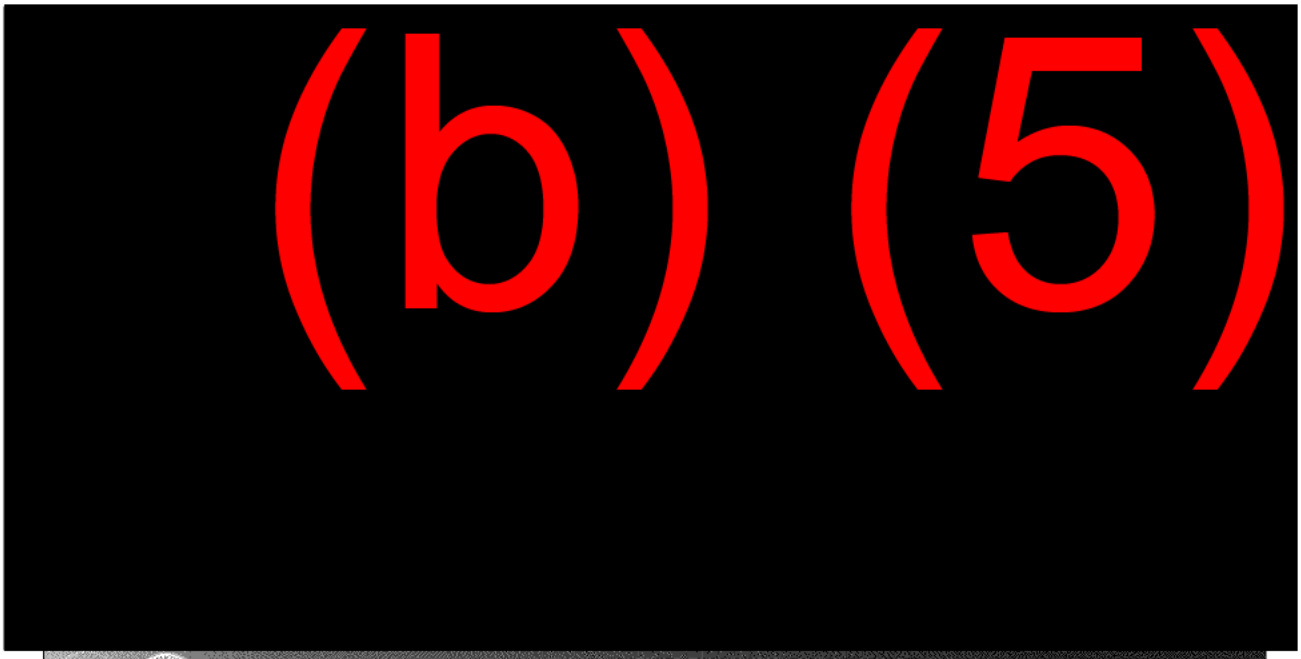


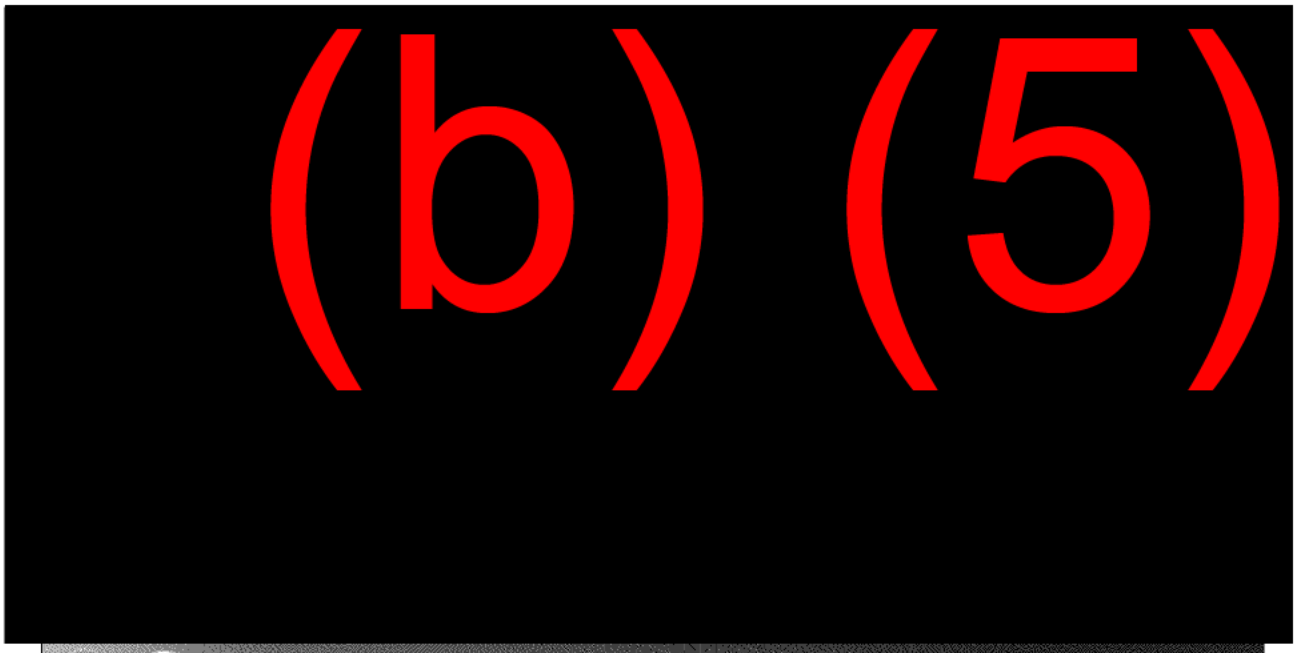
- *FOUO – For Official Use Only .Draft – PREDECISIONAL AND DELIBERATE*

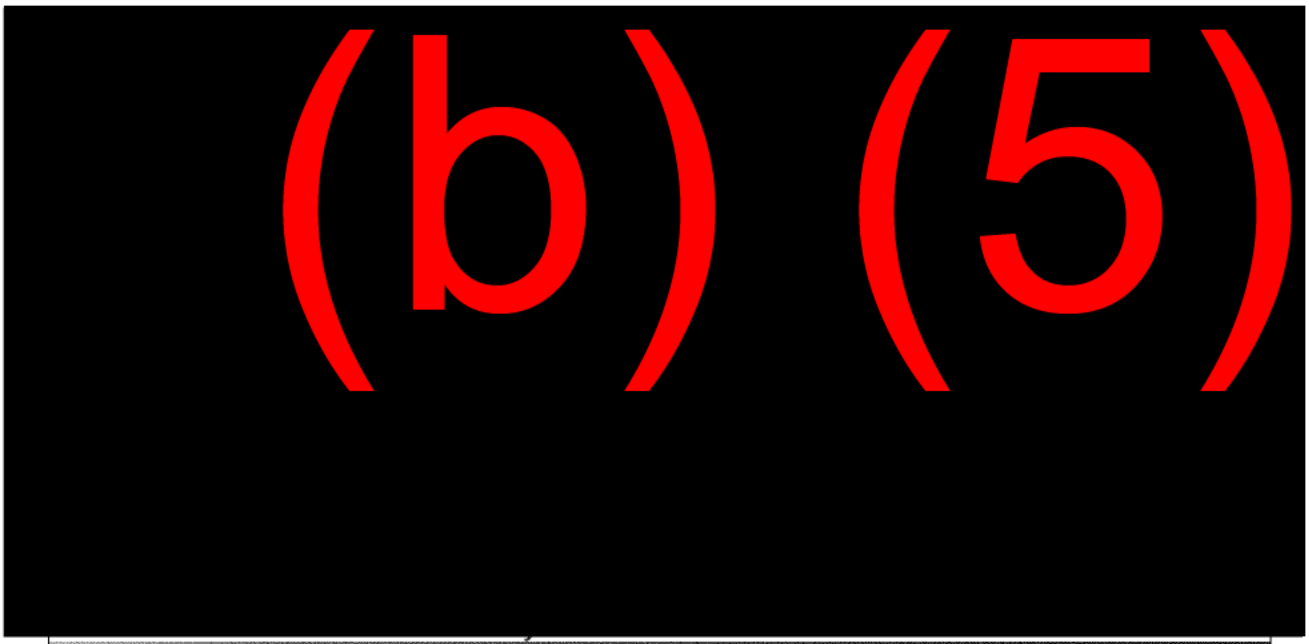


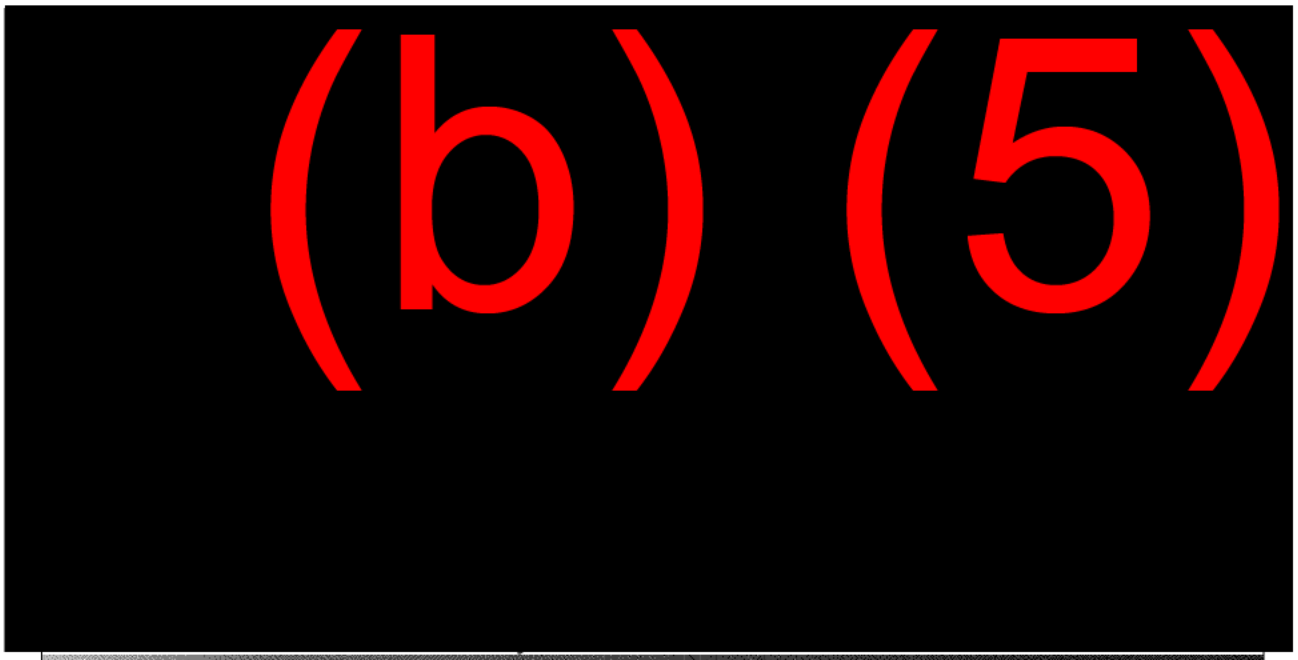


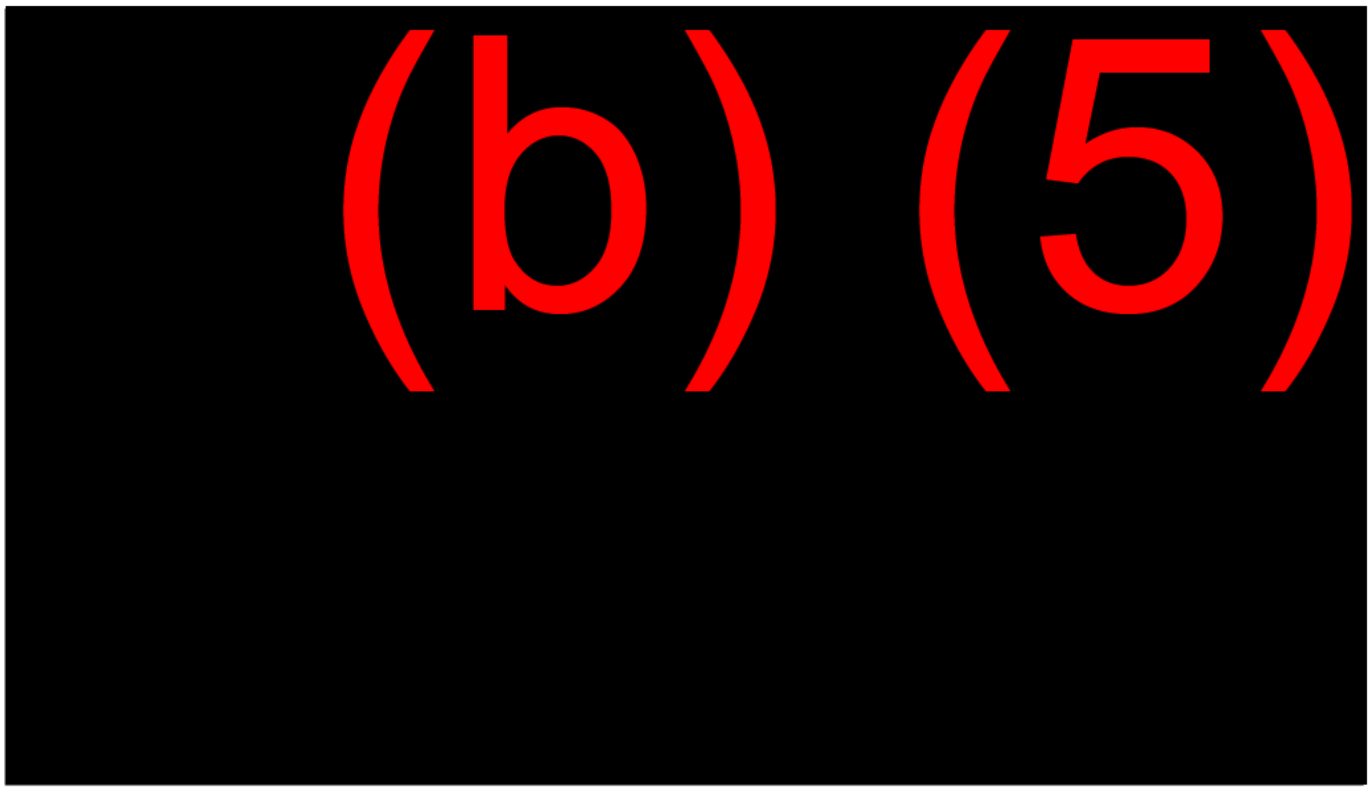


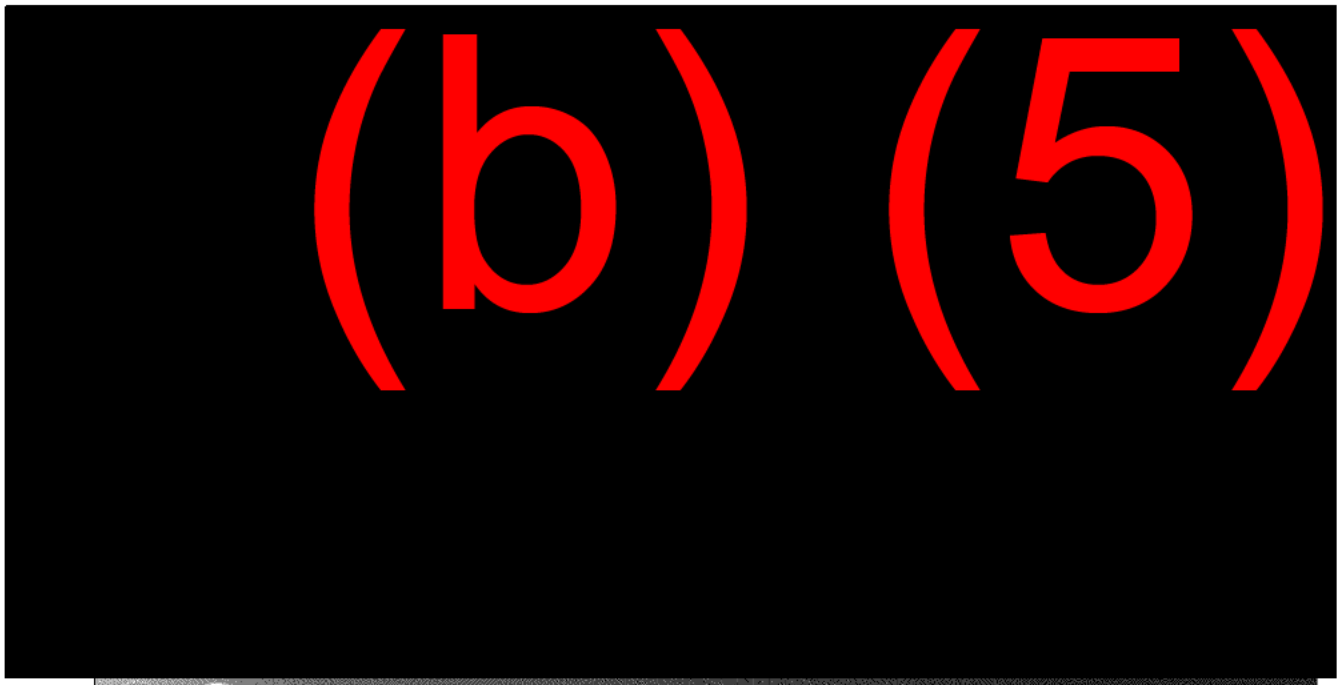


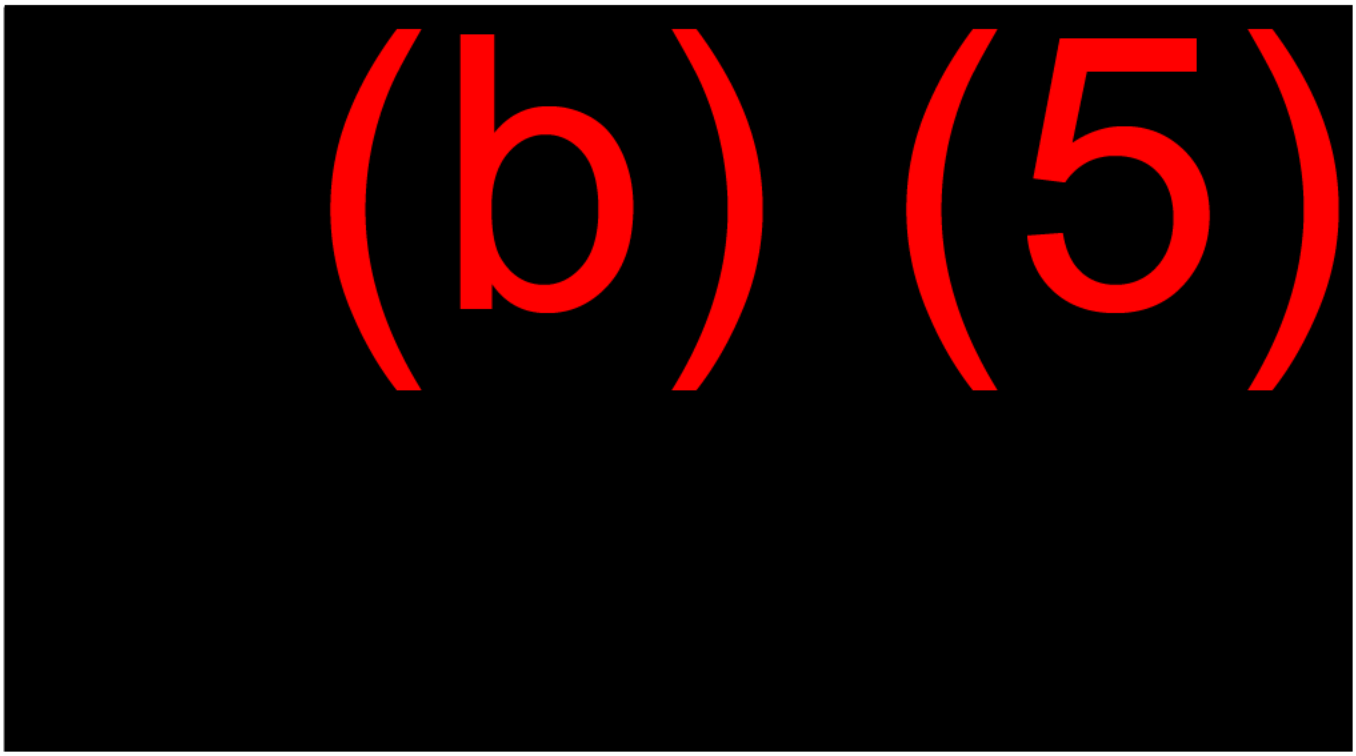


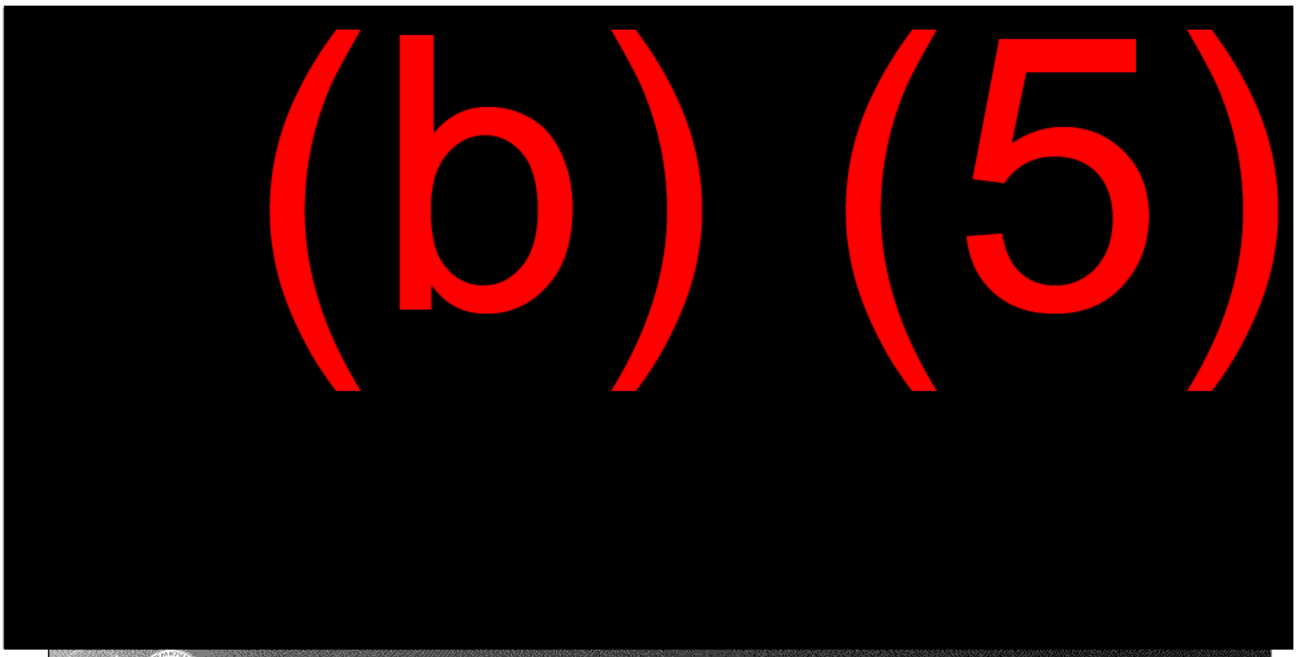


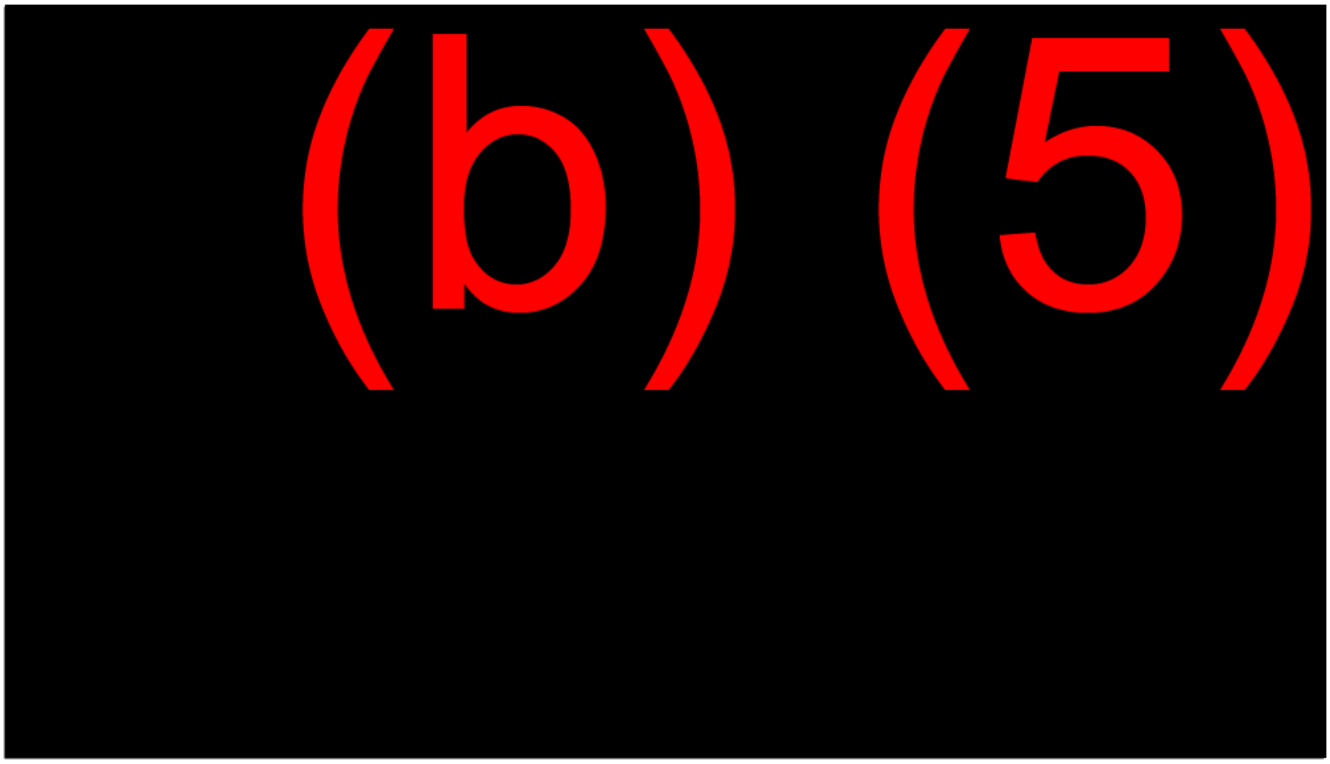


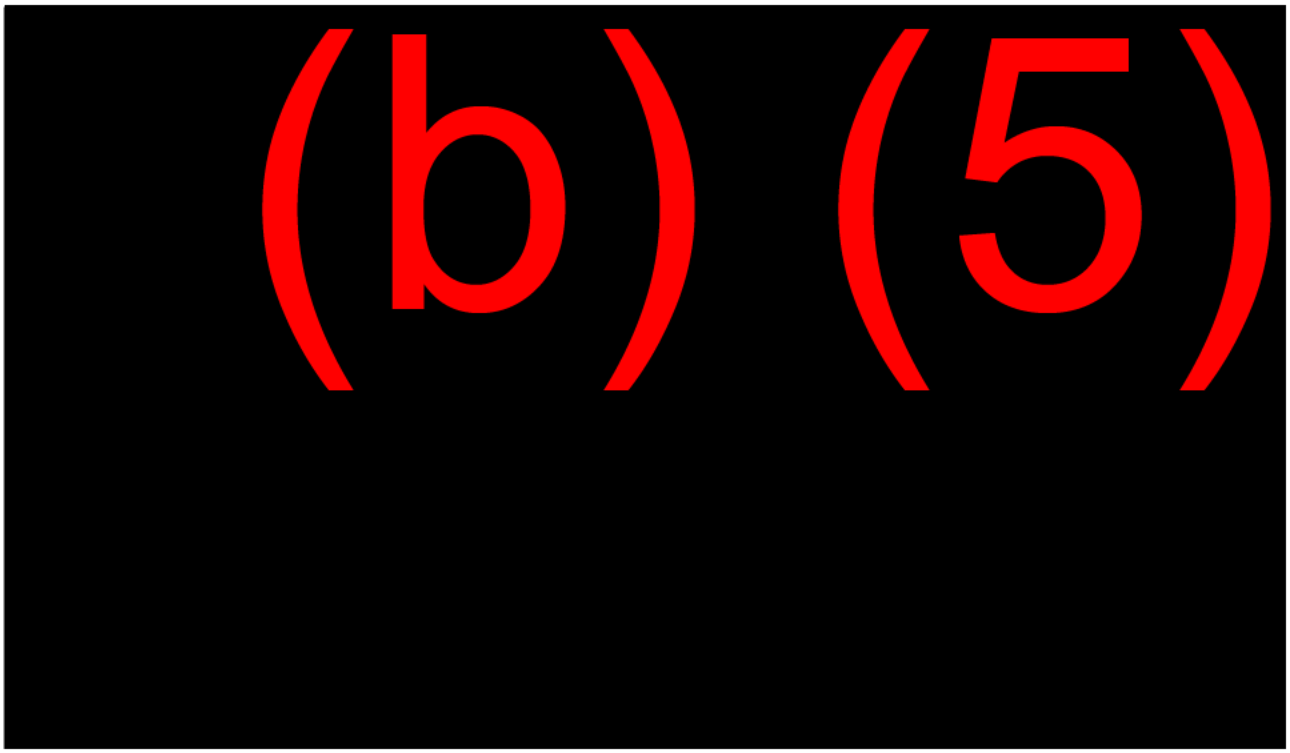

(b) (5)

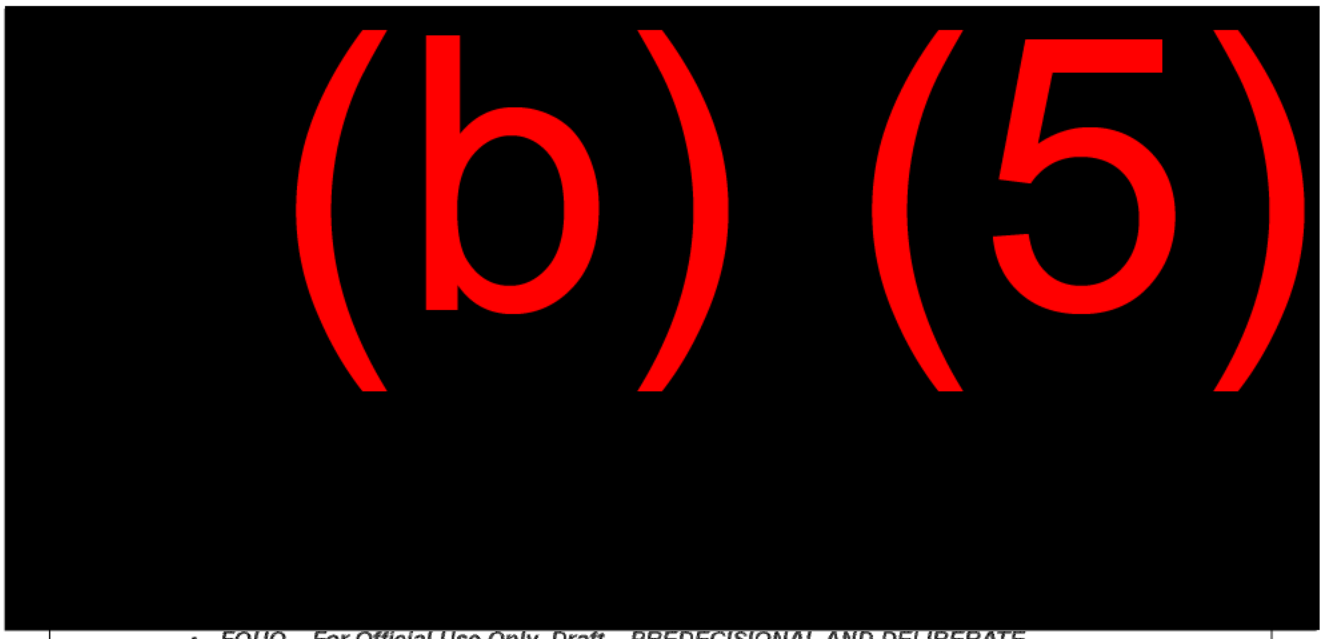


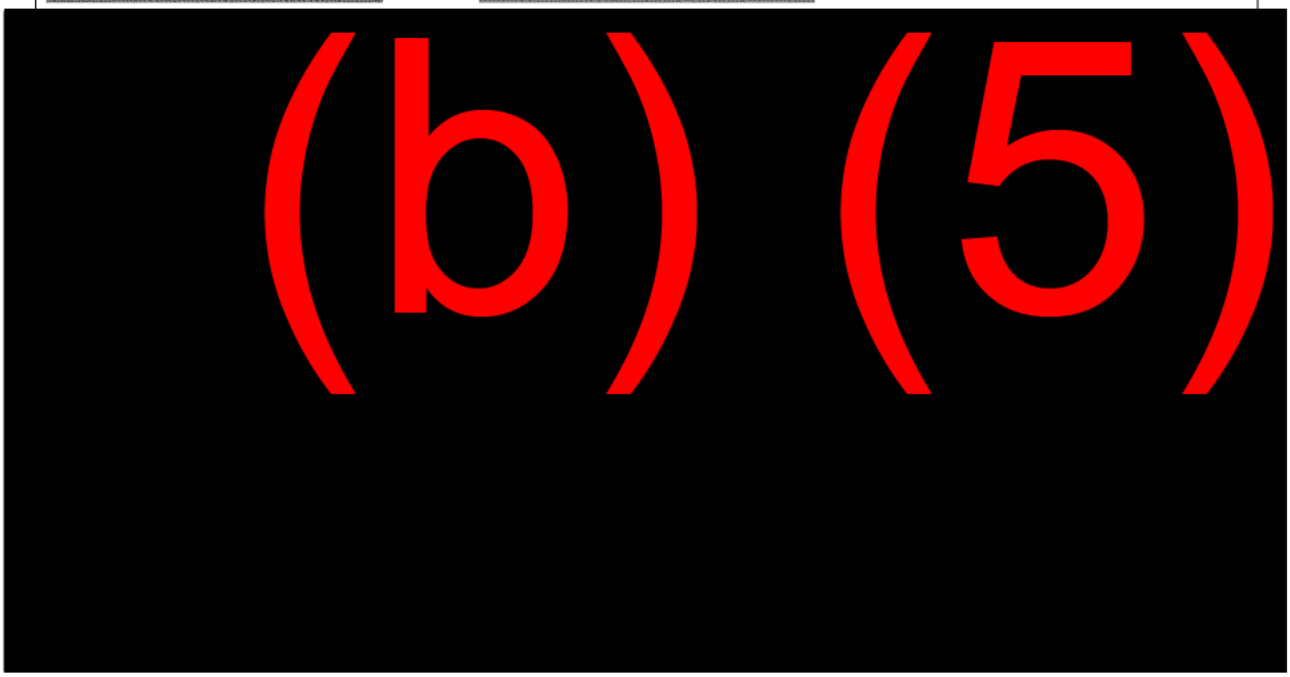

(b) (5)




(b) (5)


(b) (5)

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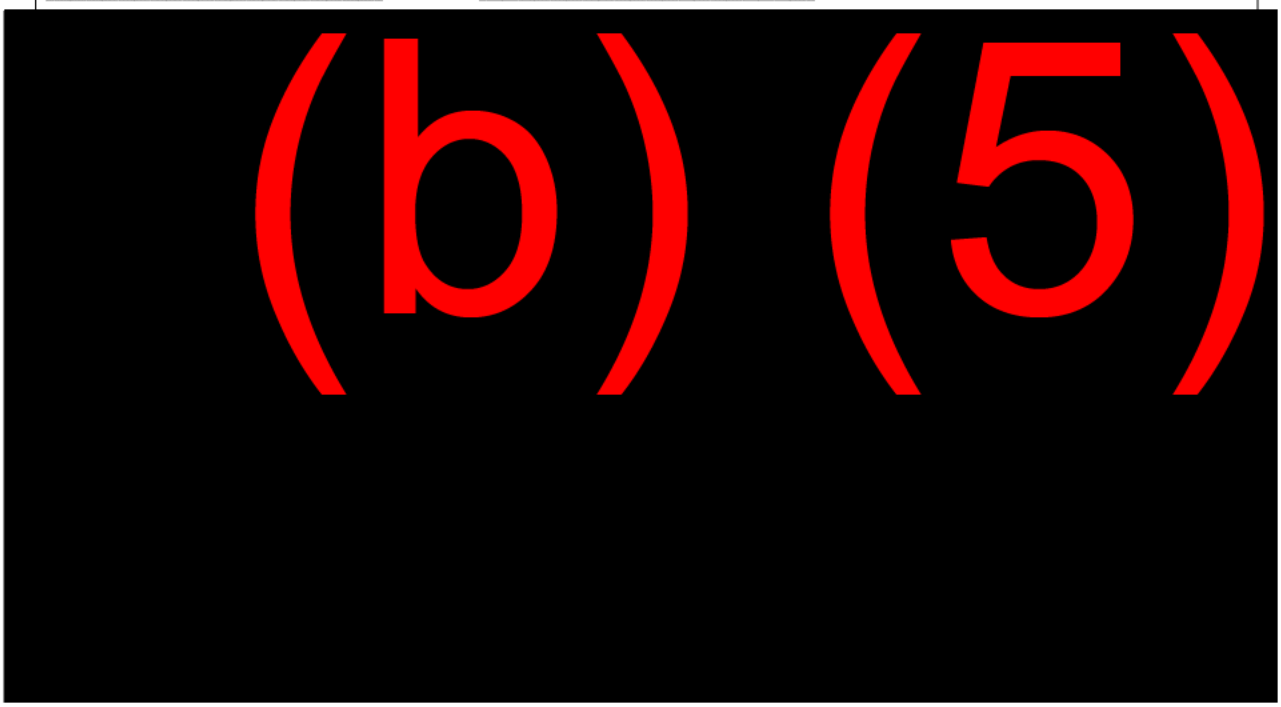
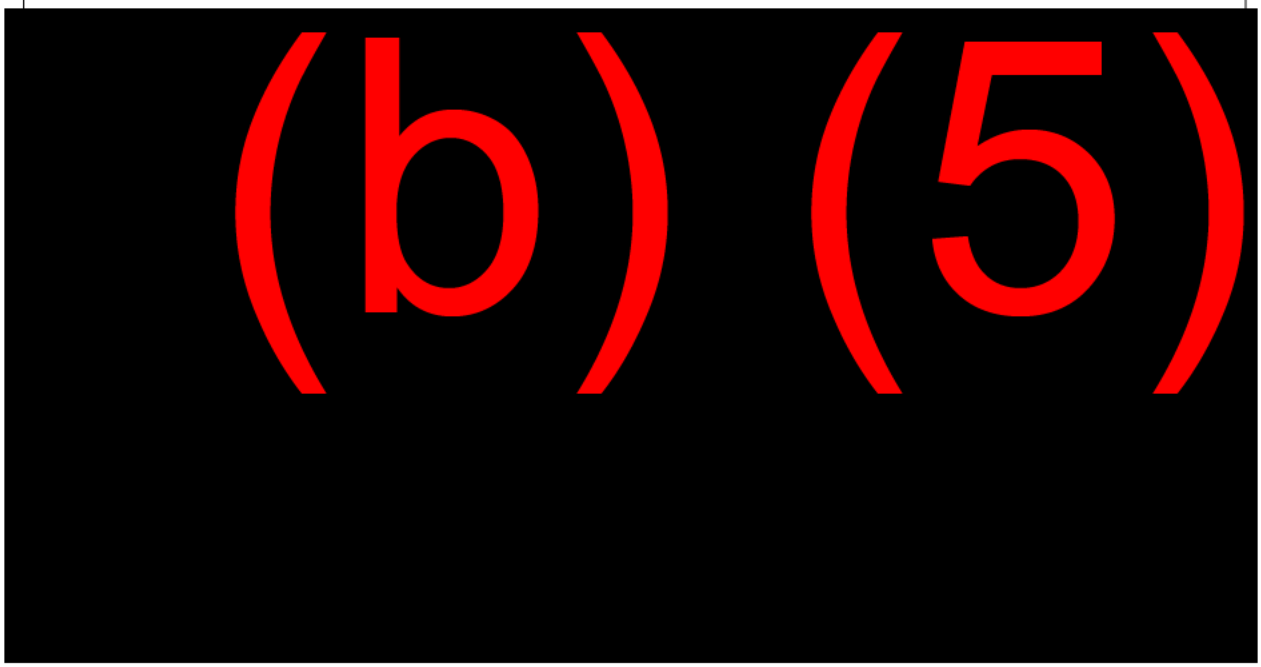
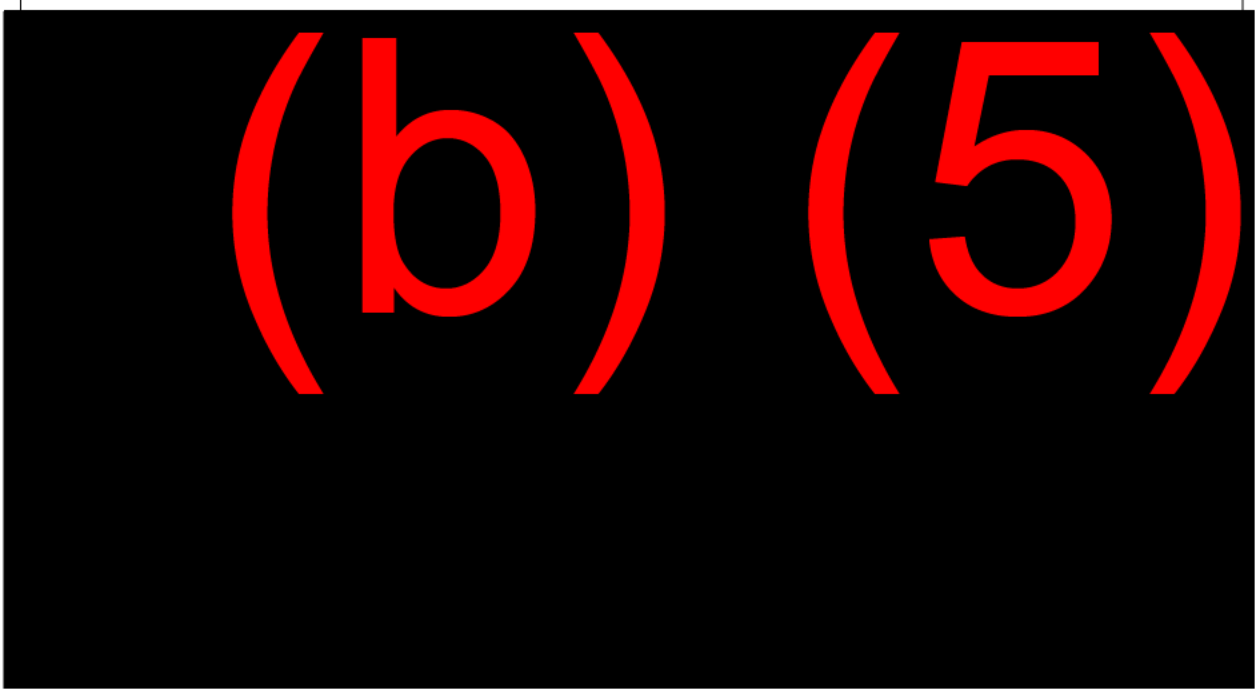
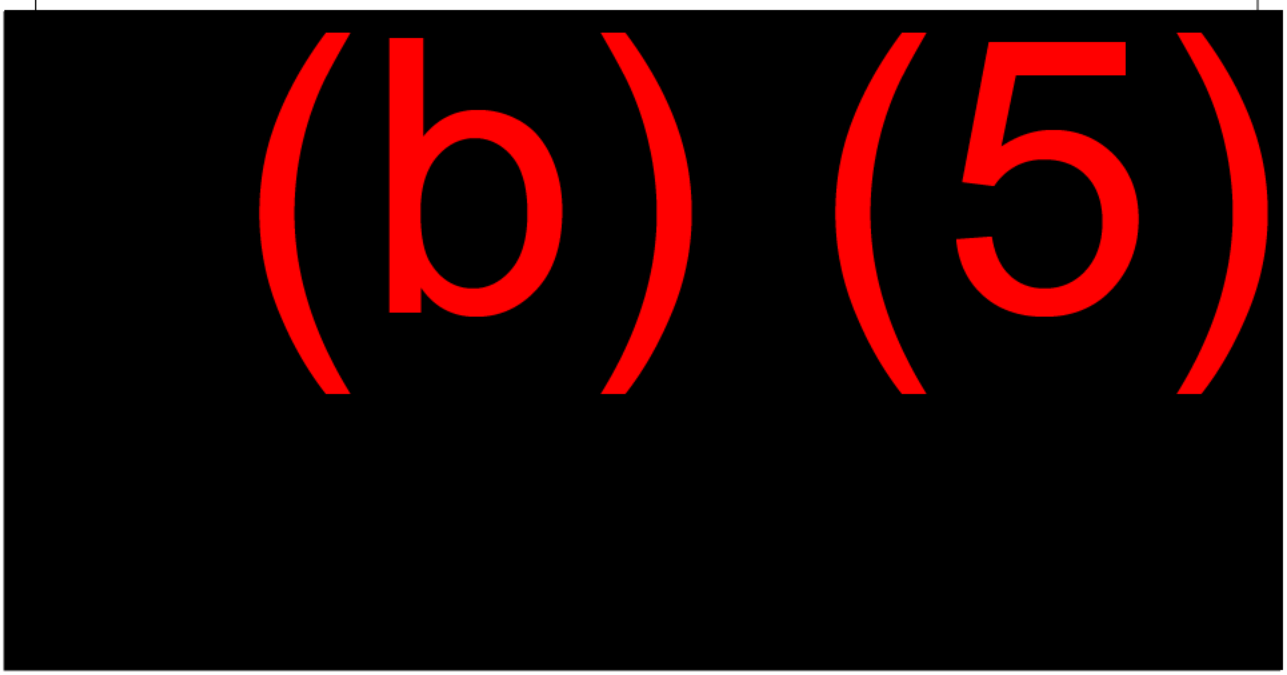
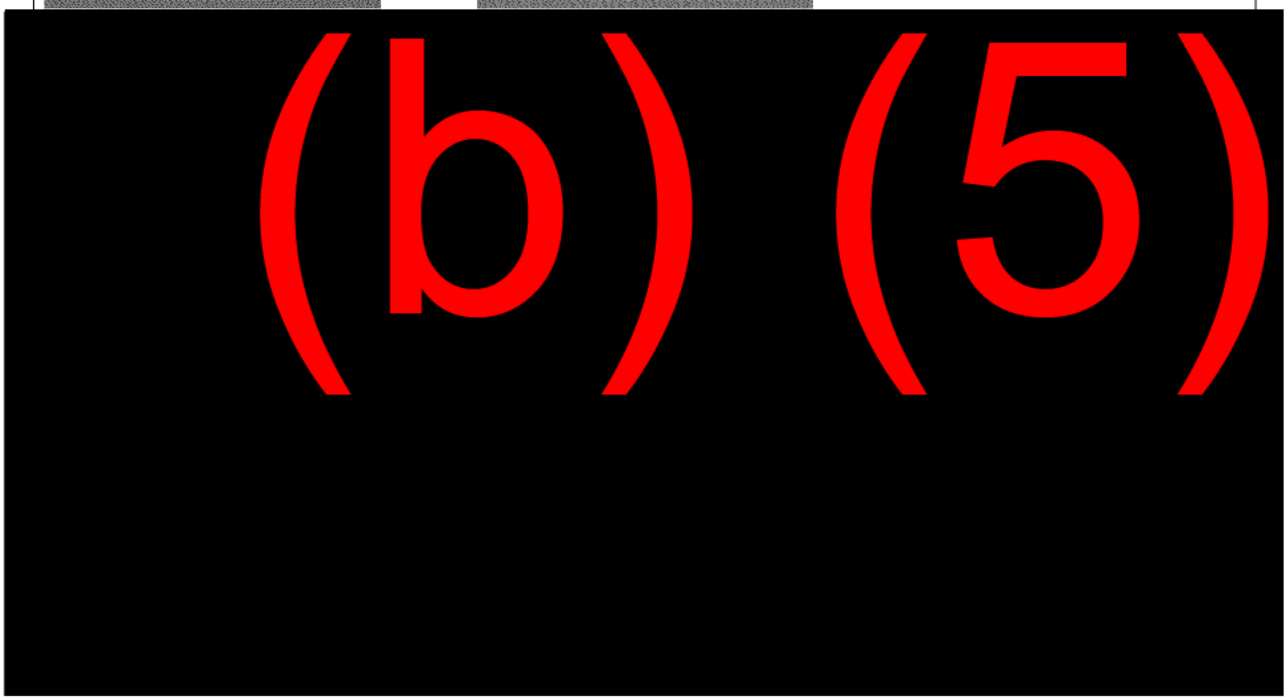

(b) (5)


(b) (5)


(b) (5)


(b) (5)


(b) (5)

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 4/17/2020 2:07:20 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: Rapid Testing -- ANTIBODY TESTING

Steve sorry missed your call. Tried you back it wen to vm.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, April 17, 2020 1:26 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; [redacted] (b) (6)>; Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Sharpless, Norman (NIH/NCI) [E] [redacted] (b) (6)>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>; Adam Boehler <[redacted] (b) (6)>
Subject: RE: Rapid Testing -- ANTIBODY TESTING

Validation by NCI is in process.
We are reviewing multiple EUAs from manufacturers including point of care tests. The manufacturers are performing the studies needed for validation and we are working closely and daily with them.
Steve

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: April 16, 2020 at 3:15:39 PM EDT
To: [redacted] (b) (6) [redacted] (b) (6)>, Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>, Sharpless, Norman E (NIH) <[redacted] (b) (6) Hahn, Stephen <SH1@fda.hhs.gov>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>, Adam Boehler <[redacted] (b) (6)>
Subject: RE: Rapid Testing -- ANTIBODY TESTING

Great
They need to be evaluated by FDA/CDC/NCI
Dr Sharpless and Dr Hahn copied

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: [redacted] (b) (6)>
Sent: Tuesday, April 14, 2020 2:42 PM
To: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>; Kadlec, Robert (OS/ASPR/IO)

<Robert.Kadlec@hhs.gov>; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: MBX WHO SR ADV FOR POL COVID Action <[redacted] (b) (6)>; Adam Boehler [redacted] (b) (6)
Subject: Re: Rapid Testing -- ANTIBODY TESTING

Resending to get ADM Giroir in the loop.

From: "[redacted] (b) (6)>
Date: Tuesday, April 14, 2020 at 2:40 PM
To: "Navarro, Peter K. EOP/WHO" <Peter.K.Navarro@who.eop.gov>, Robert Kadlec <Robert.Kadlec@hhs.gov>, Brett Giroir <BGiroir@tpevc.com>, Tammy Beckham <Tammy.Beckham@hhs.gov>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>, Adam Boehler [redacted] (b) (6)
Subject: Re: Rapid Testing -- ANTIBODY TESTING

Peter,

Looping in ADM Brett Giroir and Tammy Beckham who lead this charge for HHS and the Testing Task Force. They are in process of evaluating dozens of antibody tests.

[redacted] (b) (6)

From: "Navarro, Peter K. EOP/WHO" <Peter.K.Navarro@who.eop.gov>
Date: Tuesday, April 14, 2020 at 2:34 PM
To: Robert Kadlec <Robert.Kadlec@hhs.gov>, "[redacted] (b) (6)>
Cc: MBX WHO SR ADV FOR POL COVID Action [redacted] (b) (6)>, Adam Boehler [redacted] (b) (6)
Subject: FW: Rapid Testing -- ANTIBODY TESTING

Bob, [redacted] (b) (6)

My shop did a prelim screen of this and they were field tested by CST teams in NY to good reviews. The name of the company is **Premier Biotech**. Website below. They can ship 1.5 million units by Monday and the rest of the 5 million in 4-5 days after.

Made in the USA.

Is it worth getting a proposal from them? They can make 5 million in 10 days and plenty over time.

https://protect2.fireeye.com/url?k=92cadef2-ce9fd722-92caefcd-0cc47a6a52de-334c3de2dc02e224&u=https://protect2.fireeye.com/url?k=dd0af757-815eee2b-dd0ac668-0cc47adc5fa2-4da2af1f194414bd&u=https://premierbiotech.com/innovation/

723 Kasota Avenue SE
Minneapolis, MN 55414

From: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>
Sent: Tuesday, April 14, 2020 9:01 AM
To: McCommas, Brendan N. EOP/WHO <Brendan.N.McCommas@who.eop.gov>

Cc: Miller, Joanna R. EOP/WHO <Joanna.R.Miller3@who.eop.gov>; MBX WHO SR ADV FOR POL COVID Action <[redacted]
Subject: RE: Rapid Testing

Steve, please evaluate please. If good we can move up chain

From: McCommas, Brendan N. EOP/WHO <Brendan.N.McCommas@who.eop.gov>
Sent: Monday, April 13, 2020 7:55 PM
To: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>
Cc: Miller, Joanna R. EOP/WHO <Joanna.R.Miller3@who.eop.gov>; MBX WHO SR ADV FOR POL COVID Action [redacted]>
Subject: Rapid Testing

Hi Dr. Navarro – I just wanted to pass along the attached document describing a test using antibodies for COVID-19.

I have been working with Dr. Hatfill and Joanna to get these rapid tests out and there are 120 with the CST team up in NY to test. The company makes the tests in Minnesota and they can make 5 milion in 10 days. Mexico has already bought 5 million of the tests.

Brendan

Brendan McCommas
Special Assistant to the President
Office of Trade and Manufacturing Policy
(C) 202-881-7449
The President's two simple rules: "Buy American, Hire American."

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 5/15/2020 9:40:38 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Belew, Yodit [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3498722efcf48e19d2900a772a65413-BELEWY]
CC: Anderson, Michael [Michael.Anderson@ucsf.edu]; Garrett, Andrew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84cf75bfe35243aea04b0c91bc72c9f8-HHS-Andrew.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]
Subject: RE: DO you have a POC fro the Peds MIS-CIssue

Thank you Keagan and Steve appreciate the recommendation and we will integrate him with our team and the one that Brett Giroir has stood up. Best Bob

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, May 15, 2020 9:37 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Belew, Yodit (FDA/CDER) <Yodit.Belew@fda.hhs.gov>
Cc: Anderson, Michael <Michael.Anderson@ucsf.edu>; Garrett, Andrew (OS/ASPR/EMMO) <Andrew.Garrett@hhs.gov>
Subject: RE: DO you have a POC fro the Peds MIS-CIssue

Sir, we would recommend Dr. Belew. Dr. Belew is a pediatric ID physician in CDER who has been our lead working on pediatric COVID-19 natural history studies.

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Friday, May 15, 2020 8:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Anderson, Michael <Michael.Anderson@ucsf.edu>; Garrett, Andrew (OS) <Andrew.Garrett@hhs.gov>
Subject: RE: DO you have a POC fro the Peds MIS-CIssue

Ooops thank you

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, May 15, 2020 8:14 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>
Cc: Anderson, Michael <Michael.Anderson@ucsf.edu>; Garrett, Andrew (OS/ASPR/EMMO) <Andrew.Garrett@hhs.gov>
Subject: Re: DO you have a POC fro the Peds MIS-CIssue

Adding Steve's correct email.

Sent from my iPhone

On May 15, 2020, at 8:09 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Good morning Steve we are putting together a HHS group looking at the COVID19 syndrome in kids and wondered if you had any one in your agencydesignated to the follow the issue. If you could please share the name and contact info would be much obliged. Best Bob

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/18/2020 6:18:58 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Team,
Anand Shah, Deputy Commissioner, reached out to the Stanford investigators on our behalf. Very interesting information regarding their research and the test that they are using. They are interested in partnering with us. I'll let Anand give the details.

Anand will be reaching out to the MGH folks, as well. [redacted (b) (5)]
Steve

From: Fauci, Anthony (NIH/NIAID) [E] [redacted (b) (6)]>
Date: April 18, 2020 at 3:38:39 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) [redacted (b) (6)]>
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/18/2020 3:25:36 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

We can certainly work with them. Does anyone know any of these folks?

From: Fauci, Anthony (NIH/NIAID) [E] (b) (4) [redacted]
Date: April 18, 2020 at 10:51:33 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) (b) (6) [redacted] >
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/18/2020 10:31:07 AM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

Tony,
We have not authorized a lateral flow test yet for use as described. We have a significant number of serology tests under review and NCI is still validating some of the others.

We are working with a lot of laboratories and manufacturers and take our responsibilities in this area very seriously. We are very happy to work with all parties and have, in fact, done so. I have a regular call with the American Public Health Laboratory leadership and have offered to work closely on the tests that they and their stakeholders are using. I also have a regular call (weekly of late) with lab test manufacturers to discuss progress and attempt to remove any roadblocks.

Yesterday, we posted new FAQs and additional communications regarding the tests that have been authorized as well as our efforts with NCI to provide additional transparency to the validation data. Those communications also encourage engagement with FDA.

I am open to your suggestions on how we can further engage with parties who are doing testing of which we are unaware. I think the team on this email string could also continue to message that if a group is using a test not authorized by FDA, they must either engage with us for technical assistance or perform their own validation. Glad to discuss further.
Steve

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6) [redacted]>
Date: April 18, 2020 at 10:03:32 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>
Subject: FW: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 4/18/2020 6:31:03 PM
To: Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: medRxiv: COVID-19 Antibody Seroprevalence in Santa Clara County, California

We'll work on putting it together.
S

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6) [redacted]
Date: April 18, 2020 at 6:21:44 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lane, Henry C (NIH) (b) (6) [redacted]>, Shah, Anand <Anand.Shah@fda.hhs.gov>
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Sent: 6/14/2020 4:29:19 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
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To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.gov>, "Sherman, Susan (OS)" <Susan.Sherman@HHS.GOV>, "Barry, Daniel J (OS)" <daniel.barry@hhs.gov>, "Redd, John T (OS)" <John.Redd@hhs.gov>
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Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>
Subject: RE: EUA for Remdesivir

Bob
We can consider revision of the EUA at any time, especially on the allocation and distribution conditions. If those responsibilities were shifted to (b) (4) their sale would still be limited to the scope of the authorized uses (severe hospitalized COVID). So the EUA could be amended to allow for distribution by (b) (4) of product procured by (b) (4) or for commercial sale. Glad to discuss further.

Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: June 14, 2020 at 4:31:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Barry, Daniel J (OS) <daniel.barry@hhs.gov>, Redd, John T (OS) <John.Redd@hhs.gov>
Subject: RE: EUA for Remdesivir

Thanks I just wanted to give you a potential head start for what may be a bit of a rush should the secretary decide that we are going to proceed with a commercial alternative to USG procurement. Thanks Best Bob

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From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 14, 2020 4:29 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>
Subject: Re: EUA for Remdesivir

Bob,
We are working on an answer. I'll give you a call.
Steve

From: Robert Kadlec <Robert.Kadlec@hhs.gov>
Date: Saturday, June 13, 2020 at 2:39 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.gov>, "Sherman, Susan (OS)" <Susan.Sherman@HHS.GOV>, "Barry, Daniel J (OS)" <daniel.barry@hhs.gov>, "Redd, John T (OS)" <John.Redd@hhs.gov>
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Thank you

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 6/13/2020 2:39:12 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Barry, Daniel J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a27773dc40564218b76dc8ec50ceb0d5-HHS-daniel.]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]
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Thank you

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From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 6/14/2020 4:30:55 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Barry, Daniel J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a27773dc40564218b76dc8ec50ceb0d5-HHS-daniel.]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]
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Thank you

Bob

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 7/9/2020 4:27:19 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; (b) (6) state.gov]
Subject: Fwd: URGENT CLEARANCE: AM to Deputy M, (b) (6)

(b) (5)

Sent from my iPhone

Begin forwarded message:

From: "Koneff, Douglas A" (b) (6) @state.gov>
Date: July 9, 2020 at 4:10:01 PM EDT
To: "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>, (b) (6) " (b) (6) @state.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Cc: "(b) (6) @state.gov>, "Redd, John (OS/ASPR/IO)" <John.Redd@hhs.gov>, "Beers, Donald (FDA/OC)" <Donald.Beers@fda.hhs.gov>, "Putnam, Kate M" <Consult HHS >, (b) (6) @state.gov>
Subject: Re: URGENT CLEARANCE: AM to Deputy M, (b) (6)

(b) (5)

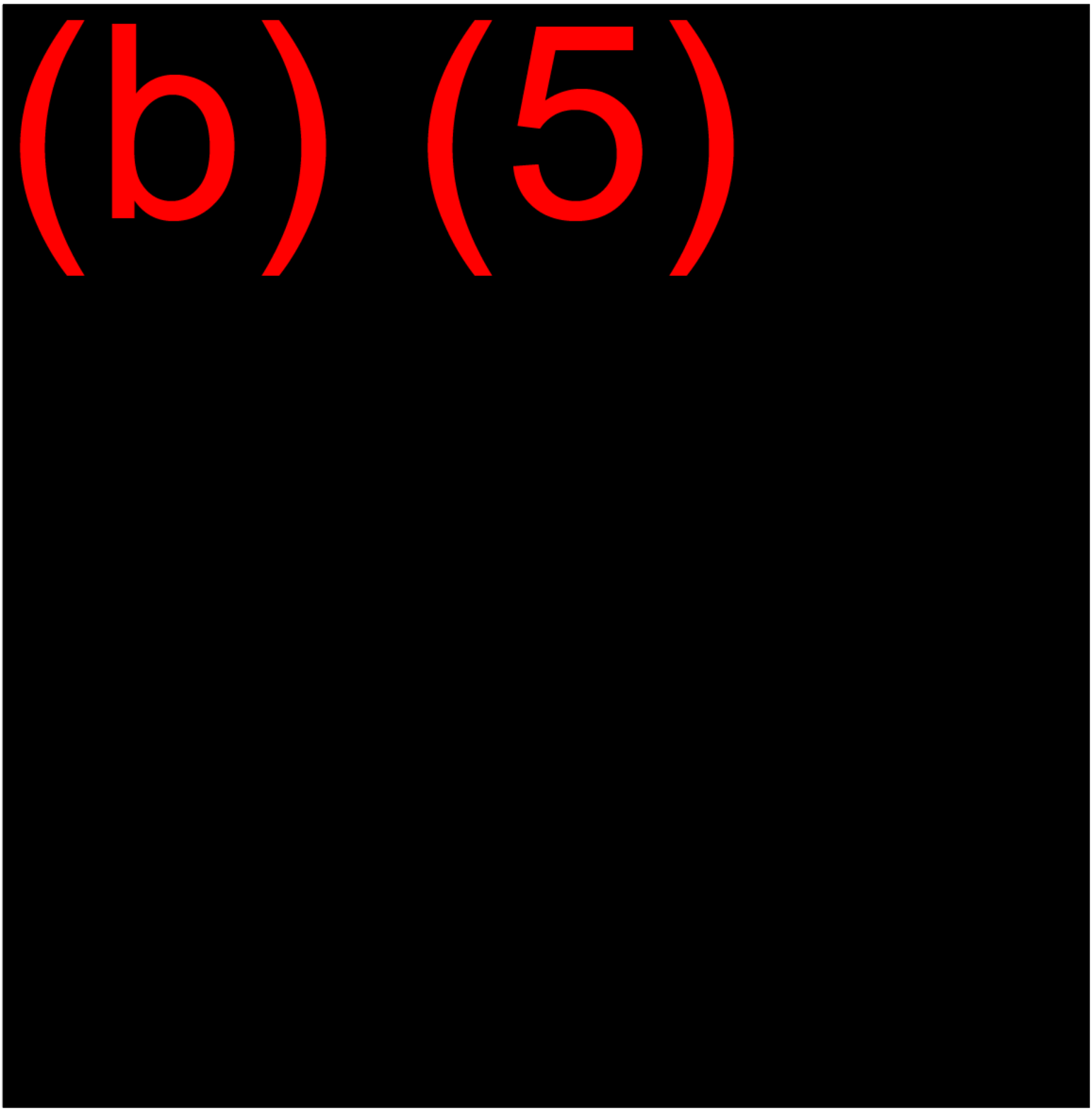
My cell number is (b) (6)

Doug Koneff

Get Outlook for iOS

From: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Sent: Thursday, July 9, 2020 3:58 PM
To: (b) (6) Kadlec, Robert (OS/ASPR/IO)
Cc: (b) (6) Koneff, Douglas A; Redd, John (OS/ASPR/IO); Beers, Donald (FDA/OC)
Subject: RE: URGENT CLEARANCE: AM to Deputy (b) (6)

(b) (5)



From: (b) (6) @state.gov>
Sent: Thursday, July 9, 2020 3:40 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Cc: (b) (6) @state.gov>; Koneff, Douglas A <KoneffD@state.gov>; Redd, John (OS/ASPR/IO) <John.Redd@hhs.gov>
Subject: RE: URGENT CLEARANCE: AM to Deputy M (b) (6)

+ Susan Sherman

From: (b) (6)
Sent: Thursday, July 9, 2020 3:38 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) @state.gov>; Koneff, Douglas A (b) (6) @state.gov>; John.Redd@hhs.gov
Subject: RE: URGENT CLEARANCE: AM to Deputy M, (b) (6)

Robert, we need to move this quickly – any update from your side, or is there a phone we can try?

Thanks,
(b) (6)

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Thursday, July 9, 2020 1:55 PM
To: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Cc: Redd, John (OS/ASPR/IO) <John.Redd@hhs.gov>; (b) (6) @state.gov>
Subject: FW: URGENT CLEARANCE: AM to Deputy M, (b) (6)

Susan can you please advise me on this time sensitive issue for State. Thank you

---

From: (b) (6) @state.gov>
Sent: Thursday, July 9, 2020 1:43 PM
To: Redd, John (OS/ASPR/IO) <John.Redd@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: (b) (6) @state.gov>; Koneff, Douglas A (b) (6) @state.gov>; Putnam, Kate M (b) (6) nsc.eop.gov>; (b) (6) @state.gov>; (b) (6)
Subject: FW: URGENT CLEARANCE: AM to Deputy M, (b) (6)

John, Robert,

(b) (5)

Please let me know if you have any questions related to this request – I'm available at the contact info below.

Many thanks in advance,
(b) (6)

(b) (6) | (b) (6) | cell: (b) (6)

SENSITIVE BUT UNCLASSIFIED

From: (b) (6)
Sent: Thursday, July 9, 2020 1:23 PM
To: (b) (6) @ >
Cc: (b) (6) @state.gov>; Koneff, Douglas A (b) (6) @state.gov>; Putnam, Kate M <(b) (6) @nsc.eop.gov>
Subject: FW: URGENT CLEARANCE: AM to Deputy M, (b) (6)

Cody,

Could you please provide guidance on obtaining the appropriate HHS clearance (see highlighted text below and bracketed language in AM document)? We need this clearance ASAP.

Many thanks,
(b) (6)

SENSITIVE BUT UNCLASSIFIED

From: (b) (6) @state.gov>
Sent: Thursday, July 9, 2020 1:03 PM
To: (b) (6) @state.gov>; MED Front Office <MEDFrontOffice@state.gov>
Cc: Koneff, Douglas A (b) (6) @state.gov>; (b) (6) Legal-WHA-DL <Legal-WHA-DL@state.gov>; (b) (6)
Subject: Re: URGENT CLEARANCE: AM to Deputy M, (b) (6)

(b) (5)

In any event, please let us know if there is anything you would like to discuss further. Thanks,

(b) (6)

From: (b) (6) @state.gov>
Sent: Thursday, July 9, 2020 12:27 PM
To: MED Front Office <MEDFrontOffice@state.gov>
Cc: Koneff, Douglas A (b) (6) @state.gov>; (b) (6) @state.gov>; (b) (6) @state.gov>; (b) (6)

(b) (6) Legal-WHA-DL <Legal-WHA-DL@state.gov>
Subject: URGENT CLEARANCE: AM to Deputy M, (b) (6)

(b) (6), (b) (5)

I am available to answer any questions you may have related to this clearance request.

Many thanks,
(b) (6)

| cell: (b) (6)

SENSITIVE BUT UNCLASSIFIED

From: (b) (6)
Sent: Thursday, July 9, 2020 7:34 AM
To: Koneff, Douglas A (b) (6) @state.gov>; (b) (6) >; Legal-WHA-DL <Legal-WHA-DL@state.gov>; WHA-PPC-Policy <WHAPPCPolicy@state.gov>; MED HART nCoV <medhartncov@state.gov>; Legal-EMP-DL <Legal-EMP-DL@state.gov>; (b) (6)
Cc: BP FrontOffice (Staff) <BP_FrontOfficeStaff@state.gov>; MEDCS (K & Gift Fund Mgt) <MEDCS@state.gov>; (b) (6)
Subject: OOB CLEARANCE: AM to Deputy M, (b) (6)

Colleagues,

I've updated the documents to include your edits and have changed the format to a **memo to Deputy M**. Kindly requesting all remaining clearances ASAP this morning, including L.

Many thanks for your continued support of this process.

Best,
(b) (6)

(b) (6) | (b) (6) | cell: (b) (6)

From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 6/14/2020 8:17:10 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Barry, Daniel J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a27773dc40564218b76dc8ec50ceb0d5-HHS-daniel.]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]
Subject: RE: EUA for Remdesivir

Steve thanks for the speedy response and clarity of what is the art of possible. Again , Gilead would have to request such modifications correct? Best Bob

---

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 14, 2020 8:15 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>
Subject: RE: EUA for Remdesivir

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Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Barry, Daniel J (OS) <daniel.barry@hhs.gov>, Redd, John T (OS) <John.Redd@hhs.gov>
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Thank you

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Sent: 7/16/2020 11:32:05 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]
Subject: FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine
Attachments: Letter for Assitant Secretary Kadlec.pdf

Importance: High

Keagan and Kyle just wanted to make you aware of the attached request from the Israeli MOD. Would defer to you how and who should be the recipient. Best Bob

---

From: Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>
Sent: Thursday, July 16, 2020 10:43 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>
Subject: FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine
Importance: High

Boss—
This is the letter from Gen Edri re assistance with an FDA contact, per discussion earlier today.

Chris

From: Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>
Sent: Wednesday, July 15, 2020 3:59 PM
To: Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine
Importance: High

Dr. Hassell and Bryan,

I received the email below from the Israeli Ministry of Defense representative here in the US. He requested that this letter from Mr. Edri go to Dr. Kadlec, but I decided it should be routed through you first. They are also interested in dropping off a hard copy at HHH at the convenience of whomever can meet them outside to receive it. Please advise.

Regards,
Jack

Jack Herrmann, MSEd, NCC, LMHC
Director (Acting), National Healthcare Preparedness Programs
Office of Emergency Management and Medical Operations, Readiness Division
Office of the Assistant Secretary for Preparedness and Response

HEALTH AND HUMAN SERVICES (DHHS) | Thomas P. O'Neill Federal Building | 200 C Street SW | Washington, DC 20515
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jack.herrmann@hhs.gov | www.phe.gov

From: Mod-dep <Mod-dep@mod.gov.il>
Sent: Wednesday, July 15, 2020 2:35 PM
To: Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>
Cc: MOD-att <MOD-att@mod.gov.il>
Subject: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine

Dear Jack,

Following our call – attached is the letter for Assistant Secretary Kadlec, please let me know that he got it.

Stay safe,

Ori Katzav
Senior Advisor for Policy & Defense Cooperation

Ministry of Defense | Embassy of Israel in the US
Office: 202-364-5608
Email: mod-dep@mod.gov.il

#WLou

State of Israel

For Official Use Only

July 13th, 2020

The Honorable
Robert Kadlec, M.D.
Assistant Secretary for Preparedness & Response (ASPR)
Department of Health and Human Services

Dear Dr. Kadlec,

During the last 5 months, at the direction of our Prime Minister, the Israel Biological Research Institute (IIBR) has initiated an accelerated R&D effort in an attempt to develop a vaccine against the SARS-CoV-2 virus.

As part of this effort, we are in a close exchange with our regulatory agency at the Israeli Ministry of Health. One of our greatest challenges is turning out to be the regulatory one, since our regulator has relatively little experience in vaccine licensing. As a result, we have been asked by our Ministry of Health to approach you in asking for your assistance in facilitating a possible cooperation between our regulators and the FDA.

The proposal is for the FDA to accompany the Israeli regulator, thus assisting us in this new and intricate process. I believe that this possible cooperation could prove beneficial for both sides – obviously for Israel, but also for the US, as the outcome would hopefully be another approved vaccine effort, with the US gaining close insight to our R&D effort. Mostly, I believe this would be very much in line with the spirit of cooperation between our two countries.

Ministry of Defense, HaKirya Tel-Aviv, 61909. Tel: 03-6976964 Fax: 03-6975841
E-mail: Moshe_edri@mod.gov.il

Bob, I am aware of the huge challenge the US is facing with CoVid-19, and the tremendous work you and your office are accomplishing in this struggle. Let me assure you that we are ready and willing to support you in any way we can.

Setting up this cooperation between our regulatory agencies would be a significant step for Israel and our joint cooperation.

Sincerely yours,

Moshe Edri

Assistant Minister of Defense

for CBRN Defense

Cc: Ministry of Health, Deputy Director General for Information and International Relations, Ms. Einav Shimron

Ministry of Health, Director of the International Relations Division, Dr. Asher Shalmon

Ministry of Defense. HaKirya Tel-Aviv, 61909. Tel: 03-6976964 Fax: 03-6975841
E-mail: Moshe_edri@mod.gov.il

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 6/14/2020 8:46:22 PM
To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Barry, Daniel J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a27773dc40564218b76dc8ec50ceb0d5-HHS-daniel.]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]
Subject: Re: EUA for Remdesivir

Correct
Steve

Sent from my iPad

On Jun 14, 2020, at 8:17 PM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Steve thanks for the speedy response and clarity of what is the art of possible. Again , Gilead would have to request such modifications correct? Best Bob

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 14, 2020 8:15 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>
Subject: RE: EUA for Remdesivir

Bob
We can consider revision of the EUA at any time, especially on the allocation and distribution conditions. If those responsibilities were shifted to (b) (4) their sale would still be limited to the scope of the authorized uses (severe hospitalized COVID). So the EUA could be amended to allow for distribution by (b) (4) of product procured by (b) (4) or for commercial sale. Glad to discuss further.
Steve

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Date: June 14, 2020 at 4:31:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Barry, Daniel J (OS) <daniel.barry@hhs.gov>, Redd, John T (OS)

<John.Redd@hhs.gov>
Subject: RE: EUA for Remdesivir

Thanks I just wanted to give you a potential head start for what may be a bit of a rush should the secretary decide that we are going to proceed with a commercial alternative to USG procurement. Thanks Best Bob

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From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 14, 2020 4:29 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>
Subject: Re: EUA for Remdesivir

Bob,
We are working on an answer. I'll give you a call.
Steve

From: Robert Kadlec <Robert.Kadlec@hhs.gov>
Date: Saturday, June 13, 2020 at 2:39 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.gov>, "Sherman, Susan (OS)" <Susan.Sherman@HHS.GOV>, "Barry, Daniel J (OS)" <daniel.barry@hhs.gov>, "Redd, John T (OS)" <John.Redd@hhs.gov>
Subject: EUA for Remdesivir

Commissioner

ASPR has been asked to draft a course of action (COA) paper for the Secretary on future procurement and allocation of remdesivir. The Gilead donation of ~ 940,00 vials of the produt is expected to be delivered by end of June and depleted by early July. Gilead is offering sale of the product in July which will be a limited amount ~360,000 vials [though not yet finally confirmed] combined for the months of July and August. By their own estimates the amount of finished drug will increase incrementally and significantly in the months of September, October and November.

The COA's being considered for this paper include a federal procurement of product in July and August or possibly enabling commercial sale of remdesivir with federal allocation of the drug under the Defense Production Act in light of its limited availability, particularly during the summer months. One of the issues that has surfaced has been the EUA that FDA issued restricts the product to the federal government and the purpose of this email is to ask whether FDA would be willing to reissue this EUA if the company requested so.

Your response would be factored into the draft document. This document would be subject HHS Exec Sec review.

Thank you

Bob

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To: Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]
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Subject: RE: EUA for Remdesivir