From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/13/2020 6:59:10 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: NY press release and updates
Attachments: NYS action_3.12.20_for PRN.docx

PR cleared and pushing out now. Your draft **(b)(5)** Your all hands comm cleared OCC, reconciling final edits and then will come to me to clear ASPA/VP.

From: Raza, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5811A7D72EE34AA78FF3C8CCB59F92EE-MRAZA]
Sent: 3/13/2020 7:20:41 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Ray Gorrie, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24cd3c82cff7486092d01d85fb1956a7-HHS-Jennife]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Benor, David E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4b600f66d50459a969e193ba8aadde5-HHS-david.b]; Tress, Deborah W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14527db4b4224120928a31d5c995408f-HHS-dew3-cd]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]
CC: Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
Subject:
Attachments: **(b)(5)**

(b)(5)

From OGC Food and Drug Division – per Ms. Amin's email below, updated memo attached.

Mark Raza
Food and Drug Division
OGC

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 13, 2020 12:16 AM
To: Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Benor, David E (OS) <david.benor@hhs.gov>; Tress, Deborah W (CDC) <dew3@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Severino, Roger (OS) <Roger.Severino@hhs.gov>; Schuham, Aaron D (OS) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Jenny, Brenna (OS) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE **(b)(5)**

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Cc: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>
Subject: RE **(b)(5)**

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Sent: Thursday, March 12, 2020 9:53 PM
To: Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Benor, David E (OS) <david.benor@hhs.gov>; Tress, Deborah W (CDC) <dew3@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Severino, Roger (OS) <Roger.Severino@hhs.gov>; Schuham, Aaron D (OS) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (OS) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>
Subject: RE **(b)(5)**

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Sent: Thursday, March 12, 2020 9:12 PM
To: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Rav-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhsgov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>
Subject: RE (b)(5)

A few line edits for consideration
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From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Thursday, March 12, 2020 8:45 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Rav-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>
Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>
Subject: (b)(5)

<< File (b)(5)

Dear All,

(b)(5)

address your equities. If you have any questions, please call or write to either me or Paula. TX Bob

Robert P. Charrow
General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
(b)(6)
Email: Robert.Charrow@hhs.gov

From: Sherman, Susan (HHS/OGC) [Susan.Sherman@HHS.GOV]
Sent: 3/13/2020 7:38:14 AM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Ray Gorrie, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24cd3c82cff7486092d01d85fb1956a7-HHS-Jennife]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Benor, David E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4b600f66d50459a969e193ba8aadde5-HHS-david.b]; Tress, Deborah W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14527db4b4224120928a31d5c995408f-HHS-dew3-cd]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]; Foster, Joseph A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b88c70a10f1843c49dafb981ae48f09c-HHS-jbf7-cd]
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Subject:
Attachments: **(b)(5)**

Please see attached draft with Brian's, Jenn's, FDD, and my comments inserted, including those Mark sent in the email below.

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, March 13, 2020 7:21 AM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan

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Cc: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>
Subject: RE **(b)(5)**

From OGC Food and Drug Division – per Ms. Amin's email below, updated memo attached.

Mark Raza
Food and Drug Division
OGC

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Sent: Friday, March 13, 2020 12:16 AM
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To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>
Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>
Subject: **(b)(5)**

<< File: **(b)(5)**

Dear All,

(b)(5)

(b)(5) TX Bob

Robert P. Charrow
General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
(b)(6)
Email: Robert.Charrow@hhs.gov

From: Severino, Roger (HHS/OCR) [Roger.Severino@hhs.gov]
Sent: 3/13/2020 8:00:03 AM
To: Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Ray Gorrie, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24cd3c82cff7486092d01d85fb1956a7-HHS-Jennife]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Benor, David E (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4b600f66d50459a969e193ba8aadde5-HHS-david.b]; Tress, Deborah W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14527db4b4224120928a31d5c995408f-HHS-dew3-cd]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Schuham, Aaron D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bd872482545445db940bb03bbd1f2cb-HHS-Aaron.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]; Foster, Joseph A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b88c70a10f1843c49dafb981ae48f09c-HHS-jbf7-cd]
CC: Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
Subject:
Attachments: **(b)(5)**

Attached are OCR's edits on top of the last doc circulated (Susan's). Thanks.

From: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Sent: Friday, March 13, 2020 7:38 AM
To: Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC)

<Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>
Cc: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>
Subject: RE: **(b)(5)**

Please see attached draft with Brian's, Jenn's, FDD, and my comments inserted, including those Mark sent in the email below.

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, March 13, 2020 7:21 AM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>
Subject: RE: **(b)(5)**

From OGC Food and Drug Division – per Ms. Amin's email below, updated memo attached.

Mark Raza
Food and Drug Division
OGC

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, March 13, 2020 12:16 AM
To: Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Benor, David E (OS) <david.benor@hhs.gov>; Tress, Deborah W (CDC) <dew3@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Severino, Roger (OS) <Roger.Severino@hhs.gov>; Schuham, Aaron D (OS) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Jenny, Brenna (OS) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: **(b)(5)**

FDA issued another EUA for a diagnostic just before midnight tonight so memo will need to be updated.

Copying Mark Raza or Don Beers to handle for FDA in the morning.

From: Amin, Stacy
Sent: Thursday, March 12, 2020 10:08 PM
To: Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Benor, David E (OS) <david.benor@hhs.gov>; Tress, Deborah W (CDC) <dew3@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Severino, Roger (OS) <Roger.Severino@hhs.gov>; Schuham, Aaron D (OS) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Jenny, Brenna (OS) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>
Subject: RE **(b)(5)**

Attached are edits from FDA. I had already started editing in the first version so these edits are not added on top of Brian and Jennifer's.

<< File **(b)(5)**

From: Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>
Sent: Thursday, March 12, 2020 9:53 PM
To: Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Benor, David E (OS) <david.benor@hhs.gov>; Tress, Deborah W (CDC) <dew3@cdc.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Severino, Roger (OS) <Roger.Severino@hhs.gov>; Schuham, Aaron D (OS) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (OS) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>
Subject: RE **(b)(5)**

I added some minor edits for your consideration to Brian's version.
<< File **(b)(5)**

From: Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Sent: Thursday, March 12, 2020 9:12 PM
To: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>
Cc: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>
Subject: RE **(b)(5)**

A few line edits for consideration
<< File **(b)(5)**

From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Thursday, March 12, 2020 8:45 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Benor, David E. (HHS/OGC) <david.benor@hhs.gov>; Tress, Deborah W. (CDC/OCOO/OGC) <dew3@cdc.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Severino, Roger (HHS/OCR) <Roger.Severino@hhs.gov>; Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>
Cc: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>
Subject **(b)(5)**

(b)(5)

Dear All,

(b)(5)

(b)(5) TX Bob

Robert P. Charrow
General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
(b)(6)
Email: Robert.Charrow@hhs.gov

From: Kimberly, Brad [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08BC909ED76D49868A5FF92C3C70FB72-BRADLEY.KIM]
Sent: 3/13/2020 8:50:03 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; 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]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: TWEETS for REVIEW: Adm. Giroir // NYS and Roche

Good morning… here are two tweet topics for your review. Thank you! --Brad

===

Adm. Giroir – FRI AM

(b)(5)

NYS and Roche – FRI AM
Thread 1:

1. Yesterday, @US_FDA took two significant actions in the agency's ongoing & aggressive commitment to addressing the #coronavirus disease (#COVID19) outbreak. https://go.usa.gov/xdFMu

2. First, FDA is granting flexibility to New York State Department of Health (NYSDOH)(@HealthNYGov) authorizing certain NY state labs to begin patient testing after validating tests & providing NYSDOH validation data within 15 days in lieu of an emergency use authorization (EUA).

3. FDA is granting flexibility to @HealthNYGov based on the urgent public health need for additional testing capacity. We weighed several factors in this decision, including that the NYSDOH has a long-established framework in place for oversight of laboratory developed tests in NY.

4. Second, FDA authorized the @Roche cobas® SARS-CoV-2 test, the third EUA granted for a diagnostic test & the first commercially distributed diagnostic test to receive an EUA during the #COVID19 outbreak. This EUA was granted within 24 hours of FDA's receipt of application.

5. To expedite test access, FDA did not object to @Roche pre-positioning its test so that labs could initiate testing immediately upon EUA authorization. Because of pre-positioning, labs can run tests on Roche's high-volume platform, which greatly increases national testing capacity.

6. Additionally, more than 25 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency.

7. We encourage test developers to approach FDA & work with us. Since the beginning of the #COVID19 outbreak, over 60 developers have sought our assistance with development & validation of tests they plan to bring through the EUA process.

Individual Tweets (Evergreen):

1. To be flexible, adaptable & responsive to the nation's needs, FDA has granted flexibility to the NY State Dept of Health authorizing certain labs in NY state to test for #COVID19 after validating tests & providing validation data to NYSDOH within 15 days. https://go.usa.gov/xdFMu

2. FDA issued an emergency use authorization (EUA) to @Roche for cobas® SARS-CoV-2 test, the 1st commercially distributed #COVID19 diagnostic. We expedited access so @Roche could pre-position its test, allowing labs to begin testing immediately upon EUA authorization. https://go.usa.gov/xdFMu

3. FDA's emergency use authorization for @Roche's cobas® SARS-CoV-2 test for #COVID19 allows labs to run tests on a high-volume platform, which greatly increases national testing capacity during the #coronavirus disease outbreak. https://go.usa.gov/xdFMu

4. By exercising flexibility to @HealthNYGov, authorizing certain NY state labs to test for #COVID19 without an emergency use authorization (EUA), we hope to expedite the availability of patient testing in New York state. https://go.usa.gov/xdFMu

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | **(b)(6)**
brad.kimberly@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/13/2020 8:54:37 AM
To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; 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]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: Re: TWEETS for REVIEW: Adm. Giroir // NYS and Roche

Look good
Thx

Sent from my iPhone

On Mar 13, 2020, at 8:50 AM, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov> wrote:

Good morning… here are two tweet topics for your review. Thank you! --Brad

===

Adm. Giroir – FRI AM

(b)(5)

NYS and Roche – FRI AM
Thread 1:

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5. To expedite test access, FDA did not object to @Roche pre-positioning its test so that labs could initiate testing immediately upon EUA authorization. Because of pre-positioning, labs can run tests on Roche's high-volume platform, which greatly increases national testing capacity.

6. Additionally, more than 25 laboratories have notified us they are testing or intend to begin testing soon under our new policy for laboratory developed tests for this emergency.

7. We encourage test developers to approach FDA & work with us. Since the beginning of the #COVID19 outbreak, over 60 developers have sought our assistance with development & validation of tests they plan to bring through the EUA process.

Individual Tweets (Evergreen):

1. To be flexible, adaptable & responsive to the nation's needs, FDA has granted flexibility to the NY State Dept of Health authorizing certain labs in NY state to test for #COVID19 after validating tests & providing validation data to NYSDOH within 15 days. https://go.usa.gov/xdFMu

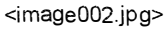
2. FDA issued an emergency use authorization (EUA) to @Roche for cobas® SARS-CoV-2 test, the 1st commercially distributed #COVID19 diagnostic. We expedited access so @Roche could pre-position its test, allowing labs to begin testing immediately upon EUA authorization. https://go.usa.gov/xdFMu

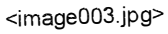
3. FDA's emergency use authorization for @Roche's cobas® SARS-CoV-2 test for #COVID19 allows labs to run tests on a high-volume platform, which greatly increases national testing capacity during the #coronavirus disease outbreak. https://go.usa.gov/xdFMu

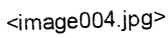
4. By exercising flexibility to @HealthNYGov, authorizing certain NY state labs to test for #COVID19 without an emergency use authorization (EUA), we hope to expedite the availability of patient testing in New York state. https://go.usa.gov/xdFMu

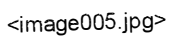
Brad Kimberly
Director, Social Media

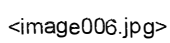
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | **(b)(6)**
brad.kimberly@fda.hhs.gov











From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/14/2020 7:27:44 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Published FP rates in China with NAT testing

Any chance you could print this for me in advance of 10 am?

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 14, 2020 at 6:22:14 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Fwd: Published FP rates in China with NAT testing

Sharing just for your information that an Oracle has been published regarding testing performed in China pertaining to false positives. According to the abstract, " In the close contacts of COVID-19 patients, nearly half or even more of the asymptomatic infected individuals reported in the active nucleic acid test screening might be false positives."

(b)(5)

(b)(5)

(b)(5)

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: March 13, 2020 at 2:51:37 PM EDT
To: CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>
Subject: Published FP rates in China with NAT testing

https://www.ncbi.nlm.nih.gov/pubmed/32133832

Zhonghua Liu Xing Bing Xue Za Zhi. 2020 Mar 5;41(4):485-488. doi: 10.3760/cma.j.cn112338-20200221-00144. [Epub ahead of print]

[Potential false-positive rate among the 'asymptomatic infected individuals' in close contacts of COVID-19 patients].

[Article in Chinese; Abstract available in Chinese from the publisher]

Zhuang GH[1], Shen MW, Zeng LX, Mi BB, Chen FY, Liu WJ, Pei LL, Qi X, Li C.
Author information

Abstract

in **English**, Chinese

Objective: As the prevention and control of COVID-19continues to advance, the active nucleic acid test screening in the close contacts of the patients has been carrying out in many parts of China. However, the false-positive rate

of positive results in the screening has not been reported up to now. But to clearify the false-positive rate during screening is important in COVID-19 control and prevention. **Methods:** Point values and reasonable ranges of the indicators which impact the false-positive rate of positive results were estimated based on the information available to us at present. The false-positive rate of positive results in the active screening was deduced, and univariate and multivariate-probabilistic sensitivity analyses were performed to understand the robustness of the findings. **Results:** When the infection rate of the close contacts and the sensitivity and specificity of reported results were taken as the point estimates, the positive predictive value of the active screening was only 19.67%, in contrast, the false-positive rate of positive results was 80.33%. The multivariate-probabilistic sensitivity analysis results supported the base-case findings, with a 75% probability for the false-positive rate of positive results over 47%. **Conclusions:** In the close contacts of COVID-19 patients, nearly half or even more of the 'asymptomatic infected individuals' reported in the active nucleic acid test screening might be false positives.

KEYWORDS:

COVID-19; Close contacts; False-positive; Nucleic acid test; Screening

PMID

32133832

DOI

10.3760/cma.j.cn112338-20200221-00144

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

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

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/14/2020 7:36:30 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Swab data

Also print
Thx

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: March 13, 2020 at 5:58:46 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>, Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: RE: Swab data

Here is the update we posted today on swabs and transport media. Primarily media has been in short supply. We are now allowing saline to be used. So any of the swabs below can be used with Saline alone. We have not heard that the swabs below are in short supply.

Q: I am having trouble obtaining viral transport media/ universal transport media (VTM/UTM) to collect and transport patient samples. Are there alternatives that I can use?
A: While VTM/UTM remains the preferred transport media, FDA believes that the following alternative transport media could be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays in a manner that will stabilize the RNA without meaningful degradation:

- Liquid Amies-based transport media.
  - Supplies:
    - E-Swab by Copan (Catalogue # 481C and 482C) with regular or flex minitip applicator
    - Opti-Swab by Puritan (Catalogue # LA-117), swab included in kit (Catalog#3317-H).
  - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

If the above are not available, FDA believes that the following could be used to collect and transport samples for molecular RT-PCR sARS-CoV-2 assays:

- Dry swab in saline
  - Supplies:
    - Puritan: 25-3317-H, 25-3316-U, 25-3316-H, 25-3317-U, 25-3318-U, 25-3318-H, 3316-U, 3317-U, 3318-U, 25-3319-H, 3316-H, 3318-H, 25-3320-U, 25-3320-U EMB 100MM, 25-3320-U EMB 80MM, 25-3320-H and 25-3320-H EMB 80MM
    - Copan: 501CS01, 503CS01, 516CS01, 518CS01 and 534CS01
  - Storage: Up to 72 hours at 4°C, or frozen for longer storage.

Please be aware that the CDC does **not** recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing.
We are continuing to evaluate other options for specimen collection supplies, and we will update this list accordingly as this information becomes available.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant

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CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, March 13, 2020 5:53 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>; Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: Re: Swab data

White House just stated that fda cleared any kind of swab for testing except naked wooden stick. Can't be true. Right?

Sent from my iPhone

On Mar 13, 2020, at 9:36 AM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

The proposed (b)(5)

(b)(5)

Jeff

From: Shuren, Jeff
Sent: Friday, March 13, 2020 9:03 AM
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>; Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>; Schwartz, Suzanne

<Suzanne.Schwartz@fda.hhs.gov>
Subject: RE: Swab data

The team is reviewing. Will circle back soon.

Jeff

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 13, 2020 at 8:55:13 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>, Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>
Subject: RE: Swab data

Standing by

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: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, March 13, 2020 8:53 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Cc: Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>; Smith, Brad (CMS/OA) <Brad.Smith@cms.hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>
Subject: Re: Swab data

Thx Brett. Jeff, I know your team is **(b)(5)** **(b)(5)** Will you get that to Brett? Thx
S

Sent from my iPhone

On Mar 12, 2020, at 11:16 PM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

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: Dan Wattendorf <Dan.Wattendorf@gatesfoundation.org>
Sent: Thursday, March 12, 2020 8:42 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Swab data

Attachment 1

Get Outlook for iOS
<CONFIDENTIAL_Data for FDA for self test at home_withSFS-COVID.pptx>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/14/2020 7:42:49 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: News from call with McKesson

Please print
Thanks.
S

From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Date: March 13, 2020 at 5:40:06 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: News from call with McKesson

Good afternoon: You asked for news from my call with McKesson today. CDRH and Brooke Courtney are also informed.

Early Surveillance of Emerging Shortages

(b) (5)

Tests and Diagnostics

1. Nasopharyngeal swabs and vials (transportation devices) for complementary testing are in shortage-- there is "no inventory" and they are under "severe allocation", i.e., seller-imposed quotas. **The shortage derives from conventional flu testing but it implies there may be no capacity to do additional COVID testing, because these swabs and vials are essential for such testing.** Orders are running about double last year's levels. **(b)(5)**

(b)(5)

2. Rapid Flu and Strep tests: Currently supplies are low. They are concerned that if these tests become required before COVID-19 testing, then supplies would be inadequate.

PPE

3. N95 Masks – Currently supplies are low. They are directing customers to HHS to get the 3M product, **(b)(5)**

(b)(5)

4. Isolation gowns – There is "no inventory". **(b)(5)**

(b)(5)

5. Gloves – Still have Nitrile gloves in stock, but concerned that if nursing homes switch to a higher level of protection, there would not be enough of those gloves

Drugs

6. IV solutions that are not produced in the U.S. Manufacturers are starting to limit sales, so these are already on allocation.

Best regards,

-Randy

202 308 0104

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/14/2020 7:51:38 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FW: Matt Bassett said to give the Admiral a call.
Attachments: HSI COVID19 BRIEF.pdf

Let's talk

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 13, 2020 at 4:55:12 PM EDT
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: FW: Matt Bassett said to give the Admiral a call.

Tim
Do you have knowledge of these, and is there any way you could make contact?
I don't know this world, but we do need new solutions

Best
Brett

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: Ettinger, Michael (Legal) <Michael.Ettinger@henryschein.com>
Sent: Friday, March 13, 2020 2:47 PM
To: Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>
Cc: Bergman, Stanley <StanleyM.Bergman@henryschein.com>; Mlotek, Mark <Mark.Mlotek@henryschein.com>; Bhansali, Seema <Seema.Bhansali@henryschein.com>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Matt Bassett said to give the Admiral a call.

Hi Carla,

Matt Bassett said to reach out to the Admiral. We called the Admiral's office, but were told to email you.

Henry Schein has identified 3 companies that have filed EUAs for lateral flow quick tests and nasal swab tests to test for COVID-19 that deliver results in 15-30 minutes. Two of these companies have been selling millions of tests in China and Korea and the third company is a start up with similar technology. We can have 40,000 tests on Monday, 1 million tests a week from now, and then in April we can ramp up to 1 million tests per day.

We are quite concerned that these tests will be sold to other countries unless the government quickly approves the EUAs and buys some tests.

The big benefit of these tests is that it can be used in the home after a telehealth encounter so that people do not have to go to hospitals and doctor offices which would stress the healthcare system beyond its capabilities.

We have a whole set of protocols that would be issued as part of this, including multiple testing, given that the antigens may not appear for several days.

Henry Schein is prepared to respond to the government's call to action and partner to alleviate the urgent need for wide availability of rapid testing. As the world's largest distributor of healthcare solutions to the office-based practitioner, we have unique reach to get these products to market quickly and educate medical professionals on best practices. Henry Schein has five strategic distribution centers across the U.S. (29 globally) which enable us to have 99% of our orders shipped the day they are received.

Henry Schein (NASDAQ: HSIC) understands that healthcare is a coordinated effort and we actively engage in discussions with the WHO, HHS, and others to be a thought-leader and private-sector partner, including in the GHSA Private Sector Roundtable and Pandemic Supply Chain Network. www.henryschein.com

Dr. Peggy Hamburg and Dr. Louis Sullivan both know us well if you need further points of reference on our company and capabilities.

If helpful, our CEO and other senior executives would welcome the opportunity to get on a phone call with you immediately to discuss the details of our plan how we can move this forward quickly before these tests get deployed to other parts of the world.

Besides myself (my contacts are below), you can reach out to our Chairman, Stan Bergman at 631.704.2852 or Mark Mlotek at 917.847.3445.

Best Regards,

Michael S. Ettinger
Senior Vice President,
Corporate & Legal Affairs and
Chief of Staff
Henry Schein, Inc.
135 Duryea Road
Melville, NY 11747
631.843.5993 (o)
631.843.5660 (f)
(b)(6) (c)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/14/2020 7:52:05 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: FW: Matt Bassett said to give the Admiral a call.
Attachments: HSI COVID19 BRIEF.pdf

Could we talk about this soon?

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 13, 2020 at 4:55:12 PM EDT
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Kellogg, Rachel (OS) <Rachel.Kellogg@hhs.gov>, Haddad, Carla (OS) <Carla.Haddad@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>
Subject: FW: Matt Bassett said to give the Admiral a call.

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Brett

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: Ettinger, Michael (Legal) <Michael.Ettinger@henryschein.com>
Sent: Friday, March 13, 2020 2:47 PM
To: Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>
Cc: Bergman, Stanley <StanleyM.Bergman@henryschein.com>; Mlotek, Mark <Mark.Mlotek@henryschein.com>; Bhansali, Seema <Seema.Bhansali@henryschein.com>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Subject: Matt Bassett said to give the Admiral a call.

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Besides myself (my contacts are below), you can reach out to our Chairman, Stan Bergman at 631.704.2852 or Mark Mlotek at 917.847.3445.

Best Regards,

Michael S. Ettinger
Senior Vice President,
Corporate & Legal Affairs and
Chief of Staff
Henry Schein, Inc.
135 Duryea Road
Melville, NY 11747
631.843.5993 (o)
631.843.5660 (f)
(b)(6) (c)

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 3/14/2020 8:51:26 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: ACLA Members Announce COVID-19 Testing

yessir

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 14, 2020 8:51 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: ACLA Members Announce COVID-19 Testing

Which meeting? The one with VPOTUS?

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: March 14, 2020 at 8:37:34 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: ACLA Members Announce COVID-19 Testing

FYI

From: Julie Khani <jkhani@acla.com>
Sent: Saturday, March 14, 2020 8:27 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: ACLA Members Announce COVID-19 Testing

Good morning, Colin. I wanted to let you know that all ACLA members who attended last week's meeting are now offering testing.

Quest Diagnostics
LabCorp
Mayo Clinic Laboratories – only testing Mayo Clinic Practice, scaling up in coming weeks
ARUP
BioReference Laboratories
Sonic Healthcare USA

Access to supplies, particularly masks and respirators, is critical. If lab employees aren't protected or become ill, they can't run tests. Urgent need. Thanks.

Julie

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Monday, March 9, 2020 8:48 AM
To: Julie Khani <jkhani@acla.com>
Subject: RE: ACLA Members Announce COVID-19 Testing

That would be great. We have a meeting at 4pm this afternoon and can raise and follow up if that works. If you can follow up on need info in the meantime that would be great so we have more detail

---

From: Julie Khani [(b)(6)]
Sent: Monday, March 9, 2020 8:44 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: ACLA Members Announce COVID-19 Testing

Very good, thanks Colin. I guess the question for now is whether the task force has given thought to whether or not private sector entities will have access to [(b)(3) 42 USC 247d-6b(d)] I'm collecting information now from my members about need, and can provide that to you.

Julie

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Monday, March 9, 2020 6:29 AM
To: Julie Khani <jkhani@acla.com>
Subject: RE: ACLA Members Announce COVID-19 Testing

Thanks for reaching out Julie. I am happy to act as an intermediary between you all and the task force. You can give my email or number [(b)(6)] to anyone who needs it and I am happy to get your messages/ questions to the task force and vice versa.

If you'd like to talk at any point today let me know

From: Julie Khani <jkhani@acla.com>
Date: March 8, 2020 at 10:55:00 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: ACLA Members Announce COVID-19 Testing

Hi Colin. I'm reaching out to you with questions about how to request or share information with the Task Force. We want to be providing information about testing capacity, etc., and there also may be occasions when we need to reach out to request information. Is there a small group of staff we should designate as a point of contact?

As an example, I heard from a member over the weekend with concerns about supplies such as N95 respirators, and wondering where to direct inquiries.

Appreciate your feedback. It is a very busy time for everyone, and we want to streamline communications.

Thanks.

Julie

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Sent: Friday, March 6, 2020 10:12 AM
To: Julie Khani <jkhani@acla.com>
Subject: RE: ACLA Members Announce COVID-19 Testing

Thank you! Will share with the boss

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

Commissioner Hahn:

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

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

Thank you.

Julie

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

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

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

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

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/15/2020 6:01:26 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: FW: Tonight's 7pm Call on Testing
Attachments: Information for Stakeholder Call on Testing.docx

Sir
1.Please make sure earlier number match this
Host Dial-In: (b)(6)
Code: (b)(6)

2. Here are questions being asked of you. I think you are covered w/ talker but lmk if you would like something else.

(b)(5)

Information for Stakeholder Call ...

Here is what you need to know:

Location: White House, Roosevelt Room

Time: Pre-Gathering: 6:45 PM
Call: 7:00 PM – 8:00 PM

Audience:
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Run of Show

Ambassador Birx – Opening Remarks, 1-2 minutes, pitches it to Secretary Azar

Secretary Azar – Opening Remarks, introduces Admiral Giroir, and asks him:

(b)(5)

(b)(5)

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov
(b)(5) cell

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/15/2020 6:13:08 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Tonight's 7pm Call on Testing
Attachments: Information for Stakeholder Call on Testing.docx; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Trueman, Laura (HHS/IEA)" <Laura.Trueman@hhs.gov>
Date: March 15, 2020 at 5:51:09 PM EDT
To: "Berkowitz, Avrahm J. EOP/WHO (b)(6), FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Redfield, Robert R (CDC)" <olx1@cdc.gov>, "Fauci, Anthony S (NIH)" <afauci@niaid.nih.gov>, "Kadlec, Robert P (OS)" <Robert.Kadlec@hhs.gov>, "Smith, Brad (CMS)" <Brad.Smith@cms.hhs.gov>
Cc: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "McGowan, Robert K (CDC)" <omc2@cdc.gov>, "Kellogg, Rachel (OS)" <Rachel.Kellogg@hhs.gov>, "Heilig, Rebecca (who.eop.gov)" (b)(6), "Pataki, Timothy (who.eop.gov (b)(6) "Hoelscher, Douglas (who.eop.gov)" (b)(6) "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.gov>, "Baker, Michael G (OS)" <Michael.Baker@hhs.gov>, "Reilly, Erin K (OS)" <Erin.Reilly@hhs.gov>, "Beck, Gary (OS)" <Gary.Beck@hhs.gov>, "Conrad, Patricia L (NIH)" <conradpa@niaid.nih.gov>, "Williams, Teresa (CDC)" <coo4@cdc.gov>, "Tignor, Beth (OS)" <Beth.Tignor@hhs.gov>, "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Pratt, Michael (OS)" <Michael.Pratt@hhs.gov>, "Heck, Mia (OS)" <Mia.Heck@hhs.gov>, "Harrison, Brian (OS)" <Brian.Harrison@hhs.gov>, "Mango, Paul (OS)" <Paul.Mango@hhs.gov>, "Apple, Matthew (OS)" <Matthew.Apple@hhs.gov>
Subject: Tonight's 7pm Call on Testing

Hi All

Thank you for participating in tonight's call on COVID-19 testing.

Here is what you need to know:

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Secretary Azar – Opening Remarks, introduces Admiral Giroir, and asks him:

(b)(5)

(b)(5)

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov
(b)(6) cell

From: Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]
Sent: 3/15/2020 6:27:56 PM
To: Secretary Scheduler (OS/IOS) [Secretary.Scheduler@hhs.gov]; AMA2 (OS/IOS) [AMA2@HHS.GOV]; Apple, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac48b1cab4934cbbbc24f6065953c815-HHS-Matthew]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Puesan, Cesar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecee77efb19b454596dbe7d7410731d4-HHS-Cesar.P]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Beck, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9eaf3460f2f04ef9a80298a7acd61e64-HHS-Gary.Be]; Brennan, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Bante, Katie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8abd9d9ceb7c4ebfba6da1cdabb56db4-HHS-Katie.B]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Williams, Teresa (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32e463e6c48413a9e21cb26fea9251b-HHS-coo4-cd]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; 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]; Smith, Brad (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8533621f52844739852d5dd666488303-HHS-Brad.Sm]

Subject: AMA prep for COVID 19 Testing call
Attachments: Information for Stakeholder Call on Testing.docx
Location: Roosvelet Room

Start: 3/15/2020 6:45:00 PM
End: 3/15/2020 7:00:00 PM
Show Time As: Busy

Recurrence: (none)

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Secretary Azar – Opening Remarks, introduces Admiral Giroir, and asks him:

(b)(5)

(b)(5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/15/2020 6:58:46 PM
To: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; 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]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: RE: AMA prep for COVID 19 Testing call

I'm not physically present because I was told I could call in.
I'm on the 7 pm line on hold
S

From: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Date: March 15, 2020 at 6:32:39 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: AMA prep for COVID 19 Testing call

This just came in for 6:45 this evening

-----Original Appointment-----
From: Secretary Scheduler (OS/IOS) <Secretary.Scheduler@hhs.gov>
Sent: Sunday, March 15, 2020 6:28 PM
To: Secretary Scheduler (OS/IOS); AMA2 (OS/IOS); Apple, Matthew (OS); Harrison, Brian (OS); Mango, Paul (OS); Puesan, Cesar (OS); Stecker, Judy (OS); Tignor, Beth (OS); Trueman, Laura (OS); Beck, Gary (OS); Brennan, Patrick (OS); Giroir, Brett (OS); Bante, Katie (OS); Redfield, Robert R (CDC); Williams, Teresa (CDC); Gershman, Lynn E (CDC); Hahn, Stephen; Sheehy, Janice; Kadlec, Robert P (OS); Ford-Barnes, Arwenthia (OS); Fauci, Anthony S (NIH); Conrad, Patricia L (NIH); Smith, Brad (CMS)
Subject: AMA prep for COVID 19 Testing call
When: Sunday, March 15, 2020 6:45 PM-7:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Roosvelet Room

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(b)(5)

(b)(5)

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Sent: 3/15/2020 6:59:24 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Clearance: Diagnostics Tweets

Thanks. Let's continue to flood the zone with good, practical information for the American people.
S

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: March 15, 2020 at 6:26:50 PM EDT
To: Shah, Anand <Anand.Shah@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Clearance: Diagnostics Tweets

We have the team on social around the townhall tonight and connected w Peter on ARC/EOP on blood donations. We offered a video and have longstanding support.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Sunday, March 15, 2020 6:24 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Clearance: Diagnostics Tweets

Steve, that's a good list.

(b)(5)

Thanks everyone

PRE-DECISIONAL, CONFIDENTIAL

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, March 15, 2020 6:11 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: Clearance: Diagnostics Tweets

Excellent
Let's go
For tomorrow let's also do some public health messaging around hand washing, attending large group meetings consistent with CDC recommendations. Let's also send something out about donating blood. **(b)(5)**

(b)(5)

Anand, any other thoughts?
S

Sent from my iPhone

On Mar 15, 2020, at 5:32 PM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Sir attached are your draft tweets per my text.

(b)(5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/15/2020 7:33:43 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: Clearance: Diagnostics Tweets

Thx

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: March 15, 2020 at 7:00:33 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: Clearance: Diagnostics Tweets

Your tweets from today that you cleared will go after the Town Hall ends.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, March 15, 2020 6:11 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: Clearance: Diagnostics Tweets

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(b)(5)

Anand, any other thoughts?
S

Sent from my iPhone

On Mar 15, 2020, at 5:32 PM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

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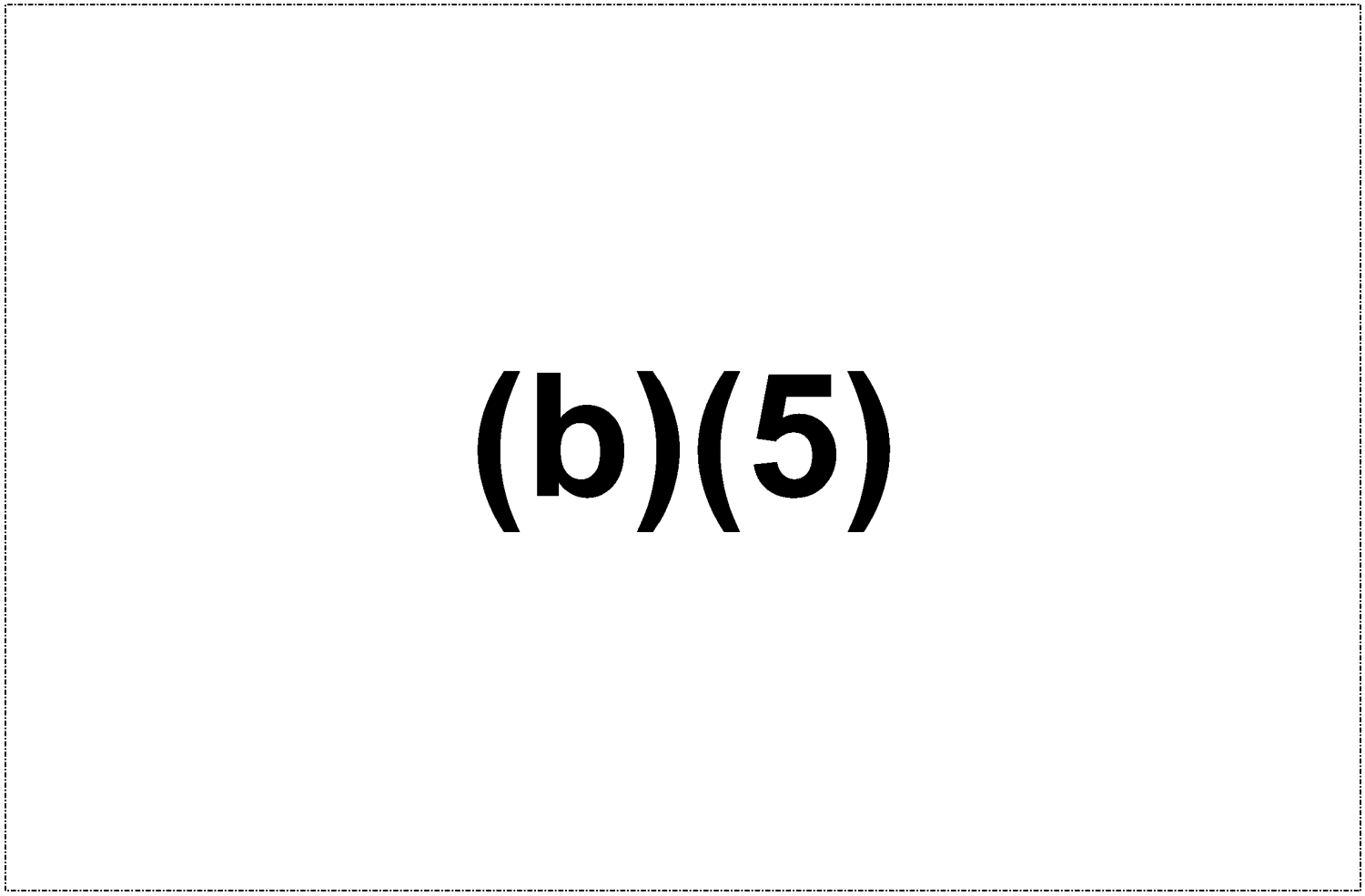
(b)(5)

From: JOHN FLYNN (b)(6)
Sent: 3/16/2020 9:09:10 AM
To: CommissionerFDA@fda.hhs.go; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: COVID-19 Countermeasure - URGENT
Attachments: Patented Mobile Surface and Air Disinfection System.pdf

Dear Dr. Hahn,

I hold a patent on a mobile disinfection system that can serve as a valuable COVID-19 countermeasure. Please review and if you deem appropriate, help me to get this information to President Trump or Vice President Pence.

As cases grow, it will be paramount to be able to rapidly and significantly reduce the two key transmission mode risks before a new patient enters a room or area previously occupied by an infected patient. The power of this system coupled with the patented cross configuration airflow design would prove highly effective at quickly inactivating COVID-19 on surfaces and within the air.

A private/public partnership would allow for the fastest way to market. There is no FDA approval necessary. It is only a question of appropriate funding and rapid engineering. **Please help as this can mitigate the spread of COVID-19.**

Thank You,

John Flynn
(b)(6)

Begin forwarded message:

From: JOHN FLYNN (b)(6)
Subject: COVID-19 Countermeasure - URGENT
Date: March 15, 2020 at 1:00:52 PM EDT
To: Secretary@hhs.gov
Cc: Robert.Johnson@hhs.gov

Dear Secretary Azar,

I reached out to Dr. Fauci's offfice, who indicated that NIAID doesn't have this type of funding capability, but that I should share this information with BARDA. I did submit this to BARDA; however, they typically don't fund this type of project as they're more dedicated to testing and vaccine development.

If you deem appropriate, I am hoping that you may know of another government avenue or if there is the ability for a special request to be made as this would provide a valuable countermeasure to COVID-19.

Please find a brief slide deck that shows some pertinent studies, in addition, to why and how this system offers a unique and effective solution to help combat this problem. There is a substantial amount of supporting information; however, I realize how busy you are and as such have attempted to be both concise and data specific.

Based upon the power of the lights and the airflow design the system will achieve approximately a (b)(4) (b)(4) This is excellent inactivation for a spore, which means even better results for a wide variety of harmful pathogens. **Viruses are particularly more susceptible to UVC both on surfaces and in the air.**

The majority of the components used to build this system are readily available products. With appropriate funding and engineering, the government can have a valuable weapon to help fight COVID-19 in a relatively short amount of time. **Please help me fight through all of the red tape and bureaucracy as this can be extremely helpful in mitigating the spread of COVID-19. Time is of the essence.**

Kind Regards,

John Flynn
Cell: (b)(6)

Begin forwarded message:

From: JOHN FLYNN (b)(6)
Subject: COVID-19 Prophylaxis - NEW STUDY
Date: March 12, 2020 at 8:27:51 AM EDT
To: Secretary@hhs.gov
Cc: Charmaine.Yoest@hhs.gov

Dear Secretary Azar,

I'm sure that you have seen this new study that was just released showing that COVID-19 can survive in the air for multiple hours and on surfaces for
days: https://www.medrxiv.org/content/10.1101/2020.03.09.20033217v1.full.pdf

This mobile disinfection system can serve as a valuable tool to reduce both transmission risks within the hospital setting, nursing home/LTC, dialysis centers and numerous other non-healthcare settings.

With your help we can quickly engineer this system and get it into the field to help prevent the spread of COVID-19. I hope that you or an appropriate member of your team will contact me.

Respectfully,

John Flynn
Cell: (b)(6)

Begin forwarded message:

From: JOHN FLYNN (b)(6)
Subject: Patented Disinfection System - COVID-19 Prophylaxis
Date: March 11, 2020 at 11:42:20 AM EDT
To: Secretary@hhs.gov

Dear Secretary Azar,

I know that you are extremely busy, but I would respectfully urge you to take 5 mins. of your time to review the information below as I believe that I have a disruptive technology that can help prevent the spread of COVID-19.

My name is John Flynn. I previously founded a startup medical equipment company that was focused within the area of orthopedics, which I ran for twelve years. I ultimately sold the company to (b)(4) (b)(4) I have worked on different healthcare projects, but have exclusively spent the last twenty months focused on a new medical product within the area of infection prevention. **My goal was to introduce what I believe is a disruptive product to help healthcare facilities to prevent the spread of MDRO's in order to reduce HAI's/SSI's; however, I believe that it can also help to reduce the spread of Coronavirus.**

UVC (ultraviolet C-wave 254nm) disinfection systems are effective in killing these pathogens missed during the manual cleaning process. The technology is well documented in multiple peer reviewed studies. The problem is that current systems use older weaker technology, only treat surfaces and are priced so high that healthcare facilities have difficulty in adequately deploying systems on a facility wide scale. There is a growing body of evidence correlating aerosolized bacteria and HAI's/SSI's. Airborne transmission and microbes that settle out of room air are a major unaddressed problem.

I am reaching out to you as I hold a U.S. patent for a UV disinfection system with what I believe to be disruptive technology. I also believe that this system could help prevent the spread of COVID-19 in numerous healthcare and non-healthcare settings.

(b)(4) (Developed by a graduate of Princeton University -MS Electrical Engineering and Harvard Business School - unfortunately passed away shortly after)

(b)(4)

(b)(4)

(b)(4) **What is also critically important is that this system is the only system capable of simultaneously disinfecting both the surfaces and the air in a room in rapid fashion.**

I believe that this system can disrupt the mobile UV disinfection industry as the only system capable of rapidly decontaminating both surfaces and the air in the room. Numerous studies are now confirming the link between aerosolized bacteria and HAI's specifically SSI's. Similar studies have demonstrated airborne transmission of pathogens are a major concern for hospitals. Two of the top ten APIC (Association for Professionals in Infection Prevention and Control) most cited articles pertain to: 1. how effective UV disinfection is at reducing colony formation on surfaces and 2. how important the transmission of airborne pathogens are and the need for procedures that can reduce the risk. Another study from APIC and AJIC released in May showed how toilet plume aerosol generation allows continual contamination of the environment with c. difficile at some distance

from the toilet. The spores become suspended and presumably travel on air currents. As Ijaz et al states, "continual redistribution of microbes indoors occurs at the air-surface-air nexus."

(b)(4)

(b)(4)

(b)(4) **This is the most effective way to disinfect air with UVC. No other mobile system has this capability. The system would be lighter and have a smaller footprint than competitors allowing for easier incorporation into workflow.** (b)(4)

(b)(4)

Rapid treatment time is essential given the critical focus on both patient room turnover time, as well as, OR turnover time.

(b)(4)

I have spoken with contract design firms who believe that this premium system can be designed and brought to market in 8 - 10 months. With appropriate resources and a larger dedicated team there is the potential to significantly reduce this timeline. All lab testing would also be completed. **A single unit could retail for approximately** (b)(4) with a recurring annual fee of (b)(4) (most manufacturers charge recurring fee's for service and reporting capability). As you may know, many UV disinfection systems currently sell for **$50,000 - $100,000 per system** (most are closer to $100K) plus recurring annual fee's of $5000 - $12,000 per system. These include: Tru-D, Xenex, Skytron, Clorox, and Surfacide. These manufacturers have layers of added costs with respect to excess materials, previous acquisition costs, debt and third party licensing considerations that prevent them from coming anywhere near the price point we are looking at.

A hospital client could deploy (b)(4) **of our systems to be incorporated within various protocols for medium to high risk areas for the same cost as 4 standard competitor systems.**

No other system could offer better, stronger technology that simultaneously disinfects both surfaces and air for a substantially lower cost.

The value to customers would be exceptional with respect to infections prevented, ROI, brand reputation, etc. No other competitor would be able to match this system's level of surface and air disinfection with respect to Log10 reductions nor would they be able to match the price point. **The system would significantly reduce all surface pathogens and it would also significantly reduce the viability of surface microbes that settle out of room air.**

The question in healthcare today is always how can we improve patient safety, enhance the patient experience and reduce costs. This system can do exactly that. My original purpose was to offer healthcare facilities a technologically advanced system that can reduce two modes of transmission risk vs one at a price that would allow adequate facility wide deployment of the technology. I do, however, believe that this system could be used as a valuable and effective tool to fight COVID-19. The value to hospitals is clear, but I also think that this could provide a cost effective solution to nursing homes/LTC, in addition to, government agencies, schools, cruise ships, airlines, prisons, etc.

I set out to develop a better solution as a result of personal experience. I have been just starting to speak with investors and have a quote from a large engineering development firm that estimates costs at (b)(4) This is not a concept as the most important element of these systems are lamp irradiance and also in our case the patented airflow design.

I am reaching out to you to see if HHS and/or other agencies would have an interest in aiding with funding and resources in order to get this system to market in the most expeditious fashion. With appropriate government resources this system could be available within months. Certainly there are no magic bullets to stop the spread of COVID-19; however, this system could absolutely help to reduce the spread if incorporated into specific protocols by being able to rapidly and simultaneously disinfect both surfaces and air within a room. If you could provide any help, I would greatly appreciate your assistance as I'm confident these systems could help in a variety of settings.

Respectfully,

John Flynn
Cell: (b)(6)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/16/2020 3:53:16 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Navarro EO

Sir – below are some talkers if you can get to Meadows and Brian with NSC to explain it would be helpful. Thanks!

(b)(5)

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/16/2020 5:16:30 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

I thought there were **(b)(5)** ?

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 16, 2020 at 3:15:32 PM EDT
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/16/2020 5:20:05 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

You are right – we clarified this to mean all labs [**(b)(5)**

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:16 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

I thought there **(b)(5)**

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 16, 2020 at 3:15:32 PM EDT
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

Thanks… consistent with WH message, let's say "up to 2000 labs" **(b)(5)**

Otherwise this is approved

Thank you

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, March 16, 2020 3:08 PM

To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

Technically "up to 2,000" according to WH and Giroir. I can tweak that.

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell (b)(6)
brad.kimberly@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 3:06 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

Hi Brad-
On tweet 4 below, is (b)(5)
Thanks,
Anand

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:19 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: COVID - Testing Availability

Good afternoon… floating this to the top of your inbox.

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell (b)(6)
brad.kimberly@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Kimberly, Brad
Sent: Monday, March 16, 2020 10:40 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: TWEETS for REVIEW: COVID - Testing Availability

Good morning… some tweets for your review. Our intent is to get these out by noon. Thanks! --Brad

===

Testing Availability
Thread

1. FDA's Center for Devices & Radiological Health is working around the clock to increase testing availability across the country. We are working closely with @CDCgov, commercial test distributors, labs & others to facilitate the distribution of tests across the country.

2. The policy we issued two weeks ago to achieve more rapid testing in the U.S. provides regulatory relief & clarity to encourage the development of new #coronavirus diagnostic tests for Americans.

3. Under this policy, we have heard from more than 40 labs, many of which have already begun patient testing.

(b)(5)

https://twitter.com/WhiteHouse/status/1239330551762432005/video/1

5. We will continue to update the American people on the availability of #COVID19 tests & their components. We are focused on making sure tests are distributed & and that test developers & labs have the materials they need to run their tests.

CDRH FAQ Individual Tweets

@SteveFDA Account

1. FDA is open 24/7 & we are here to help labs & test developers get tests into the field & the materials they need to develop the tests. Our #FAQs for labs are always updated, providing info on alternative sources of reagents, extraction kits, swabs & more. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

(b)(5)

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: (b)(6)
brad.kimberly@fda.hhs.gov

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 3/17/2020 10:01:33 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]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: Additional Background Material: Tues, March 17, 2020
Attachments: Memo--Manchin .docx

Good Morning Dr. Hahn,

Attached is the memo for your 3:30pm call with Senator Manchin. It is possible that this call may move to later but we will keep you updated. Wanted to ensure you had these materials to review in advance.

Please let me know if you have any questions.

Jakea

Jakea Copeland
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Desk Phone: (301) 796-7050
Email: Jakea.Copeland@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/17/2020 11:27:02 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: FDA request of ADx

Print for me?

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: March 17, 2020 at 9:18:49 AM EDT
To: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Cc: Bryant, Doug <dbryant@quidel.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, FDA Commissioner <Stephen.Hahn@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: FDA request of ADx

Hi Susan,

Thanks for reaching back out and for the quick call we just had. I understand Dr. Hahn is joining your meeting today and so have copied him. This is just a start. Please comment or edit as needed or wanted.

At a high level, this is the ask:

"FDA suggests companies make public their inventory, production schedule and a hotline number to address questions regarding availability of reagents and other supplies needed for COVID-19 testing. If you have an allocation plan to maximize efficient testing, please post."

It could perhaps most efficiently be done by each manufacturer creating a COVID-19 Testing Page listing the products they offer, any backorder situation, and any allocation plan.

At the moment, the testing items of greatest need are:

Swabs
Transport media
Extraction reagents
Controls
PCR reagents
Test kits
Instruments

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

Jennifer Campbell
Administrative Assistant

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

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

From: Van Meter, Susan <SVanMeter@AdvaMeddx.org>
Sent: Tuesday, March 17, 2020 8:46 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Cc: Bryant, Doug <dbryant@quidel.com>
Subject: FDA request of ADx

Tim -
Doug and I connected a short while ago on the request Jeff and you sent to me late yesterday.

Is anyone in your team available to speak with me to about potential options and exactly what you believe would be the most helpful information we could provide

We want to step up in a way that is effective and practical.

We will speak later this morning with our executive committee.

My cell is: (b)(6)

Regards,
Susan

Susan Van Meter
AdvaMedDx

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/17/2020 11:35:41 AM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Chaput, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6aee5b76fbac46349df3dbedb2e77511-HHS-Daniel.]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Nicholls, Richard (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baaee1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Ethier, Kathleen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7895b283237401cb312576b43fef452-HHS-kbe0-cd]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Macrae, Jim (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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Subject: Distribution: Summary of Conclusions - COVID-19 (3/16) Pre Disaster Leadership Group Meeting
Attachments: COVID-19-Pre DLG-Summary of Conclusions-20200316.docx

Dear Disaster Leadership Group (DLG) Members,

This email serves to transmit the attached Summary of Conclusions prepared for the COVID-19 Pre-DLG convened on March 16, 2020. We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message.

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

Thank you,

SHANTE ROBINSON, CAPM (CTR) | JR. MANAGEMENT ANAYLST, SPPR
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Sent: 3/17/2020 5:33:18 PM
To: Keagan Lenihan [Keagan.Lenihan@fda.hhs.gov]; Anand Shah [Anand.Shah@fda.hhs.gov]
CC: Colin Rom [Colin.Rom@fda.hhs.gov]
Subject: Notes on therapeutics

Vaccines

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

Plasma therapies
Joint effort of FDA/NIAID/BARDA/CBER
-convalescent plasma single donor units will be treated with pathogen reduction techniques form people with high titers of antibodies. It is expected that this treatment will reduce viremia and improve outcomes. The plan is to have this therapy available in 2 weeks and use an expanded access protocol to distribute and collect data.
-hyperimmune Immunoglobulin (Hyperimmune Ig) will be manufactured through a BARDA supported small manufacturer in North Carolina called Grifols. Hyperimmune Ig is similar to convalescent plasma with respect to expected outcome but is more convenient to administer. The expected timeframe is 6 weeks. We are waiving the usual regulatory requirement of a 60 day hold of the collected plasma.
-A critical limiting factor for plasma therapies is the assay for measuring titers on the units of collected plasma. NIAID and a manufacturer are working on this issue.

Drug Therapies
anti-virals
-Remdesivir trials are ongoing in the US and China. US trials are being performed by Gilead and NIAID

(b)(4)

-Chloroquine is an anti-malarial agent being repurposed for treatment against Covid-19. A small trial of 24 patients was performed in France.

From: Redfield, Robert R. (CDC/OD) [olx1@cdc.gov]
Sent: 3/17/2020 7:37:19 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: Connecting you with the director, re: Chloroquine & Hydroxychloroquine
Attachments: Cortegiani_JCritCare_2020.docx; Gaeo_et al_Chloroquine--COVID-19.pdf; CQ_Westward_FDA_Label.pdf; Wang_InVitro_CellResearch_2020.pdf

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From: Tan, Kathrine (CDC/DDPHSIS/CGH/DPDM) <kit4@cdc.gov>
Sent: Tuesday, March 17, 2020 7:18:13 PM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Knotts, Ashley (CDC/OD/OCS) <vqf0@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Parise, Monica E. (CDC/DDPHSIS/CGH/DPDM) <mep0@cdc.gov>
Subject: RE: Connecting you with the director, re: Chloroquine & Hydroxychloroquine

Dear Dr. Redfield and all,

Chloroquine has been observed to be effective in limiting SARS-COV2 in vitro. Published clinical trial data on its efficacy for treatment of COVID-19 are lacking.

Chloroquine is known to have anti-inflammatory effects and *in vitro* evidence that it inhibits cell entry of the virus in primate cells in culture.

Information attached:
1. Systematic review on efficacy and safety of chloroquine for treatment of COVID-19 (Cortegiana et al) – only abstract is available. Waiting on article from library.
2. Short communication about in vitro data (Wang_InVitro_CellResearch_2020.pdf)
3. Letter to the editor from Chinese scientists on clinical trials (Gao_et al_Chloroquine-COVID-19.pdf)
4. Chloroquine FDA label with general information about the drug (CQ_Westward_FDA_label.pdf)

Please feel free to call me if you have questions: 404-513-4936.

Kind Regards,
Kathrine

Kathrine R. Tan, MD MPH
Team Lead, Domestic Response Team
Division of Parasitic Diseases and Malaria/Malaria Branch
Centers for Global Health
Centers for Disease Control and Prevention
1600 Clifton Rd. MS H24-3
Atlanta, GA 30329
Office: 404-718-4701

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Sent: Tuesday, March 17, 2020 6:47 PM
To: Tan, Kathrine (CDC/DDPHSIS/CGH/DPDM) <kit4@cdc.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Cc: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Knotts, Ashley (CDC/OD/OCS) <vqf0@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Subject: Connecting you with the director, re: Chloroquine & Hydroxychloroquine

Per our chat, please send information to the director this evening by replying to this email. Thank you

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/18/2020 7:00:29 AM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: COVID-19 Therapeutics Talking Points

Thanks, Jeet

Sent from my iPad

On Mar 17, 2020, at 10:54 PM, Guram, Jeet <Jeet.Guram@fda.hhs.gov> wrote:

Dr. Hahn, please see cleared talking points attached and pasted below, with a focus on chloroquine. You'll get a copy of these in the morning with your other materials for the day. Feel free of course to email or call if you have any questions – thank you.

Therapeutics Talking Points

(b)(5)

(b)(5)

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Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner

Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

<2020.03.17 COVID Therapeutics Talking Points.docx>

From: DLGDESK (HHS/ASPR/OPP) [(b)(6)]
Sent: 3/18/2020 1:53:37 PM
To: DLGDESK (HHS/ASPR/OPP) [(b)(6)]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Smith, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Cooper, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Dodgen, Daniel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Gettinger, Andrew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17c5a2d5b6284d2ca58f9de61500f3fe-HHS-Andrew.]; Abbey, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e829e079e04eb48bdb70b832423c8f-HHS-Rachel.]; Lennon, Todd (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96a7c26cba7943b2b2f9c9009c2f94d1-HHS-TLennon]; Dasher, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Kellogg, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cochran, Norris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Cederberg, Christina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Thornton, Cody R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a7908b18a64fed92a3ddd40eb4c316-HHS-Diana.H]; Donato, Darrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59880927cd1c4c54898474f90a3cf036-HHS-Darrin.]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Robinson, Shante R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b18b5bd335f44389c02-HHS-Shante.]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Newland, Matthew J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b4f1a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; (b)(6) Ignacio, Joselito (b)(6) (b)(6) Chew, Heather (b)(6) (b)(6) Polowczyk, John P (MIL) (b)(6) (b)(6) Nguyen, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82e7178d699e4deeac3878b481d35adc-HHS-Ann.Ngu]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Borden, Cheryl Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=550d6616858b470a8f27188f4c68afbc-HHS-Cheryla]; Hrdina, Chad (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba019c157c04b6a954f7f0d2be38d4e-HHS-Chad.Hr]; Ezernack, Paige (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=872e1cb77bfe440596caae115cd6515c-HHS-Paige.E]; Evenhaugen, Stuart T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=787b151ed5be4791a81368f3e48760cc-HHS-Stuart.]; Falcon, Jessica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]; Seiler, Brittney J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bec759d8a37149dd9a94b730ff725a9b-HHS-Brittne]; Scharf-Bell, Helga (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44e4138b28db431588baaee120980be8-HHS-Helga.S]; Hunt, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aadc442d0a554b969136a5f489809f71-HHS-Richard]; Cardo, Denise M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc15bb1e3a74f7888e1305cc5337b07-HHS-dbc0-cd]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Srinivasan, Arjun (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af2edf18ecb14b1bb2f8e9ecf6172129-HHS-beu8-cd]

CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77bfb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]; Harper, Victor G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d572fe7d36f44ffe86101e5cbef9c957-HHS-Victor.]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Sprow, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64f37b83ba664226b72bbc0193dd5fff-HHS-Kyle.Sp]; Tate, Anna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b7f2e4ef1bc4e4a907d25facaafc3db-HHS-Anna.Ta]; Evans, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=707787d2aa234917a84598234c9c7661-HHS-Catheri]; Oxner, Julie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08b67fbda196471fa5ab3b113e264438-HHS-Julie.O]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]

Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19-DLG-Agenda-03-18-2020 FINAL.pdf; Hick_et_al-2006-vent triage.pdf; Assessing capacity of US HC system to use additional mechanical vents Ajao et al DMPH Dec 2015.pdf; Ventilators Status and issues DLG vFINAL 18Mar2020.pdf; COVID-19-DLG-Summary of Conclusions-20200317 FINAL.docx
Location: Conference Number: 202-774-2300, Access Code: (b)(6)

Start: 3/18/2020 3:00:00 PM
End: 3/18/2020 4:00:00 PM
Show Time As: Tentative

Recurrence: (none)

Update: Agenda and read-ahead materials are attached.

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS

Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

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

Conference Line

Conference Number: (202) 774-2300
Meeting Access Code: (b)(6)
WebEx: https://meetingserver.hhs.gov/orion/joinmeeting.do?MTID=d40fae08b1dc97bb5567609f33d88a6d

If you have any questions, please reach out to me Dan Dodgen ((b)(6) and kindly copy (b)(6)

Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

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From: Clifford Hudis [(b)(6)]
Sent: 3/18/2020 5:26:26 PM
To: Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; (b)(6)
Subject: ASCO resources if needed

Dear Drs. Verma, Hahn, Shah and Sharpless,

In this moment of deepening crisis I am writing first of all to thank you for all your efforts to help us care for our patients who need us now more than ever.

I also have a request: please let me know how ASCO can help. We stand ready to assist you in whatever way you need, whether that is sharing critical information with our members, or sharing experiences we are hearing from the front lines of patient care.

Like many other professional societies, members have turned to us for information and support in dealing with COVID-19 related issues. In response, ASCO has mobilized its resources to provide oncology professionals updates on a range of topics, including Medicare policy changes, state policies/resources, private insurer policies, clinical care management, and clinical trial information, (much of which each of you has provided) and all of this is available at https://www.asco.org/asco-coronavirus-information.

We also are providing daily updates to member questions, which largely center on treatment issues and practice safety. Our members continue to ask us about shortages of PPE, availability of masks, drug shortages, supply of ventilators, etc. Our responses, which are based on a combination of clinical evidence/literature (where available) and input from clinical experts who serve on ASCO's various guideline panels, are on the same web site above and are updated as needed.

For patients, Dr. Merry Markham, a leading ASCO expert, has authored a blog on ASCO's Cancer.Net, providing daily updates and information. At the same time we are also collaborating with the National Coalition for Cancer Survivorship (NCCS) to provide regular information on questions and concerns from cancer survivors.
https://www.cancer.net/blog/2020-03/coronavirus-2019-what-people-with-cancer-need-know

If there is more we can do or needs you see unmet where we can help please reach out. We stand ready to help.

Sincerely Yours,

Cliff

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Assistant: Sara da Silva (b)(6)

Making a w●rld ●f difference in cancer care

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/18/2020 5:34:27 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Therapeutics Press Statement (so far)

(b)(5)

Coronavirus (COVID-19) Update: FDA Continues to Facilitate Development of Medical Countermeasures to Respond to Outbreak

The following is attributed to FDA Commissioner Stephen M. Hahn, M.D.

The U.S. Food and Drug Administration continues to play a critical role in the multifaceted all-of-government response to the COVID-19 pandemic and is taking a cross-agency approach to leverage the full breadth of our public health tools as we oversee the safety and quality of FDA-regulated products for American patients and consumers. Our staff, which includes more than 10,600 physicians, pharmacists, nurses, scientists, researchers and consumer safety officers, are working around the clock to fulfill our critical public health mission. This includes, among other things, facilitating medical countermeasures to diagnose, treat and prevent the disease, and surveilling the medical product and food supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary.

Today, as part of those efforts, President Trump has directed the FDA to continue its work with the public and private sector to ensure the maximum availability of potentially safe and effective life-saving drugs to patients who are in desperate need, including those infected with COVID-19, as well as continue to exercise flexibility to enhance the Administration's ability to provide critical medical devices to affected communities.

Through our Incident Management Group, the FDA has already demonstrated our commitment to responding swiftly to this pandemic and providing regulatory flexibility and relief for medical products designed to diagnose, treat and mitigate COVID-19. Some of those measures include our work to expand diagnostic availability, allowing the use of non-FDA reviewed N95 respirators, and providing guidance to pharmacies to compound alcohol-based hand sanitizing products, with more actions to be forthcoming in the immediate future.

As part of these efforts, the FDA is working with other government agencies and academic centers to investigate the use of the drug chloroquine to determine whether it can be used to treat patients with mild to moderate COVID-19 to potentially reduce the duration of symptoms, as well as viral shedding, which can help prevent the spread of disease. We're aware of studies already being conducted with hydroxychloroquine and chloroquine, which are already FDA-approved to treat malaria, lupus, and rheumatoid arthritis. However, we need to acquire safety and efficacy data from high-quality clinical trials for treatment of COVID-19.

In particular, the FDA is working the Centers for Disease Control and Prevention, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority - a component of the U.S. Department of Health and Human Services' Office of the Assistant Secretary of Preparedness and Response - regarding a potential donation of chloroquine products by Bayer to the Strategic National Stockpile (SNS).

While BARDA maintains the SNS, the FDA is ultimately responsible for authorizing or allowing these products to be given to patients or used in clinical trials. We are working with our government and academic partners to initiate randomized controlled clinical trials to study whether chloroquine or hydroxychloroquine are effective in treating COVID-19. Please know we are working expeditiously, but we are also being cautious to not authorize products for the marketplace that may bring false hope in treating patients. Although we are working quickly, we must ensure these products are effective; otherwise we risk treating patients with a product that might not work when they could have pursued other, more appropriate, treatments. At the same time, we will also work to ensure these products continue to remain available for their approved uses in severe and life-threatening illnesses such as lupus.

We understand and recognize the urgency with which we are all seeking prevention and treatment options for COVID-19. We want to assure the American public that the FDA also continues to work with partners across the U.S. government and regulated industry to expedite the development and availability of critical medical products to prevent and treat this novel virus, including repurposing existing therapies that may help treat patients with COVID-19.

At this time, there are no FDA-approved therapeutics or drugs to treat, cure or prevent COVID-19, however there are several FDA-approved treatments that may help ease the symptoms from a supportive care perspective.

We are extremely encouraged by the interest and promise in the development of the COVID-19-related therapies that are being evaluated – and we're working closely with innovators in their work to expedite these efforts, including leveraging scientific information about the virus and trials currently being conducted in other countries such as China, Japan, South Korea and Italy as well as in the U.S.

Quickly after the emergence of this virus, the FDA began working directly with partners and innovators to foster the development of medical countermeasures against COVID-19, and we are continuing to provide regulatory flexibility, advice, guidance, and technical assistance. We continue to work with interested sponsors to help expedite any additional clinical trials for COVID-19 medical countermeasures that may be appropriate. The FDA is able to, and has been, turning around requests very quickly to assist in initiating clinical trials.

For example, last month, the NIH began a randomized controlled trial for the treatment of COVID-19 patients with Remdesivir. The FDA has been working with the drug sponsor, Gilead Sciences Inc., to find multiple pathways to both study the drug under the FDA's investigational new drug requirements, and thus collect helpful data about the efficacy of the drug, as well as provide the drug to patients under emergency use.

The FDA's efforts to facilitate the development of these therapies are squarely focused on ensuring these medical countermeasures meet the agency's world-respected gold standard, relying on data from adequate and well-controlled trials to most efficiently determine if an experimental treatment can safely and effectively benefit patients.

The role of the FDA is especially important during these times. When patients do not have FDA-approved options, it's critical we support getting patients enrolled in clinical trials that could ultimately lead to widespread use and availability of safe and effective treatments.

Innovators are looking at products in a variety of areas, including the assessment of antiviral drugs that might treat the specific virus, as well as host targets, such as interleukin-6 (IL-6) receptor inhibitors that may be helpful in reducing lung inflammation and improving lung function in COVID-19 patients – potentially slowing the progression of severe respiratory symptoms. Regeneron Pharmaceuticals Inc. has announced the initiation of a randomized controlled clinical trial of sarilumab, an antibody to the IL-6 receptor, to assess whether the modification of the inflammatory response by this treatment provides benefit to COVID-19 patients.

There's also interest in evaluating whether therapies, such as convalescent plasma and hyperimmune globulin, antibody-rich blood products that are taken from blood donated by people who have recovered from the virus, could shorten the length, or lessen the severity, of the illness. The FDA is taking the lead on an urgent cross-government approach to facilitate the development of all of these products. Facilitating the ultimate widespread use and availability of safe and effective medical countermeasures is critical for a number of reasons, including that reducing the severity and duration of respiratory or other symptoms through medical treatments could help lessen the burden on medical personnel, equipment and facilities.

The FDA will continue to support the development of those products that may lessen the severity of COVID-19, but we also recognize that we must support the availability of supportive care, such as ventilators, for those patients whose illness progresses rapidly. At this time, we are aware of supply chain pressures of ventilators and we are working expeditiously with BARDA to facilitate the availability of these devices and will share more information soon on a national mitigation strategy.

At the same time as we work to facilitate the development of treatment options in the near-term, we're also working with interagency partners, product developers, and international public health organizations to expedite the development of vaccines to the greatest extent possible. In fact, earlier this week, NIH announced

the start of a Phase 1 clinical trial in Seattle in 45 healthy adult volunteers to test the safety of an investigational vaccine designed to protect against COVID-19. The FDA intends to use all of the regulatory flexibility granted to it by Congress to ensure the most efficient and timely development of vaccines to fight COVID-19.

As we work to facilitate prevention and treatment options, it's extremely important for everyone to know that people may try to make claims about products that are not approved to actually, and don't have data supporting efficacy in preventing, treating or diagnosing COVID-19. We are closely monitoring the market to combat these products with fraudulent claims. It is unacceptable that anyone would take advantage of Americans during this public health crisis, and I want to make sure everyone knows what legitimate products are being developed.

All of this exciting work continues in parallel with our efforts supporting diagnostic development. In addition to providing regulatory relief and flexibility for those laboratories wishing to immediately begin patient testing, we are also working with test developers on innovative testing methods, including point of care testing. We've engaged with several developers who are pursuing authorization for this type of testing.

We remain steadfast in helping to foster the development of safe and effective medical countermeasures and ensuring they are available as quickly as possible to protect public health and safeguarding Americans from fraudulent products claiming to prevent, treat or diagnose COVID-19 as part of our around-the-clock response to this outbreak.

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/18/2020 7:27:54 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: FOR SH REVIEW: WH Remarks

Thank you! Yes, we will make sure it gets to them.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 7:25 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: FOR SH REVIEW: WH Remarks

Beautifully done. Approved. Can we also make sure this goes to Dr. Fauci, Dr. Redfield, and also Joe Grogan/Maria Bonner?
Thanks
STeve

Sent from my iPad

On Mar 18, 2020, at 7:21 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi Dr. Hahn,

Attached and pasted below are your draft remarks for the WH presser tomorrow. This is based on the OCC-cleared larger statement, but we would like your input on tone and content before we run back by them. If you're good with this we'll get reviewed and get you reactive talkers as well.

- Thank you, Mr. President.

(b)(5)

(b)(5)

- Thank you.

Thanks,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell **(b)(6)**
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

<WH Presser Remarks 03182020_SC mf.docx>

From: Heather Youngblood (b)(6)
Sent: 3/18/2020 9:37:58 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Expand COVID-19 Testing

Heather Youngblood
(b)(6)
March 18, 2020

Dear Stephen M. Hahn,

Dear President Trump:

I am writing as a member of our nation's laboratory medicine team, which includes pathologists and laboratory professionals, to raise my concerns about America's capacity to meet patient testing needs for COVID-19. To date, other countries are doing a better job addressing the diagnostic needs of their patients.

Our government needs to take assertive action to expand the capacity of our nation's clinical laboratories to provide diagnostic testing for the COVID-19 virus in order to hasten its containment. The United States' clinical laboratories are having difficulties securing the resources needed for COVID-19 testing. Labs need an unfettered supply of test kits, instrumentation, reagents and DNA extraction kits, as well as the virus samples necessary to accurately and reliably identify this virus. In addition, clinical labs and their vendors need enhanced regulatory flexibility to meet these needs. Commercial vendors, who have test materials to detect COVID-19, are restricted from providing guidance on the use of these products, i.e., test methods, because the tests are not FDA cleared. This restriction, which is acceptable at most times, delays the implementation of critically needed assays in times of crisis. We request that vendors are temporarily released from these restrictions and are allowed to provide guidance for testing for the COVID-19, which will facilitate the implementation and more wide-spread use of these tests.

I urge you to direct the federal government to take immediate action to help our nation's laboratories expand laboratory testing capacity needs as quickly as possible.

As a laboratory professional dedicated to providing quality patient care, I stand ready to assist you in our nation's time of need.

Sincerely,

Sincerely,
Heather Youngblood

From: Gawin, Antoinette [Antoinette.Gawin@terumobct.com]
Sent: 3/18/2020 9:42:08 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Whitaker, Scott [SWhitaker@AdvaMed.org]; Johnson, Janet [Janet.Johnson@terumobct.com]; Larson, Scott [Scott.Larson@terumobct.com]
Subject: Regulatory Barriers to Potential Therapies for COVID-19

Dear Dr. Hahn,

Thank you for your willingness to consider alternatives to our current regulatory processes. As briefly discussed, our objective is to bring technologies that are in active use to treat COVID-19 patients into the U.S. arsenal to combat this pandemic. As these are not all approved in the U.S., and some are off-label uses, we are prohibited from sharing information about their use and efficacy with health care providers. The examples below help illustrate this.

Convalescent Plasma collected on Trima

- The Chinese MOH issued unofficial guidelines authorizing the transfusion of convalescent plasma – plasma taken from a recovered patient – into critically ill COVID-19 patients. Active studies in Denmark and Austria. Experts in several European countries are using locally.

(b)(4)

Please advise the best way to further these proposals. Please do not hesitate to reach out for any additional information.

Thank you for your support,

Antoinette Gawin
President & Chief Executive Officer
TERUMOBCT
Unlocking the Potential of Blood
Office: +1.303.542.5302
Mobile: (b)(6)
TERUMOBCT.COM

From: Pat Nagy (b)(6)
Sent: 3/19/2020 12:19:40 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Coronavirus vaccine-immunology suggestion

Dr. Hahn, once your investigations have resulted in the need for immune vaccines, please, request that Novartis participate in this research. As you know, they developed Sandimmune to resist the body from rejecting organs.

Good luck and thank you for any consideration.

P.Nagy

From: Cindy Delsorbo (b)(6)
Sent: 3/19/2020 12:49:10 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Question on Testing a Person with a High Immune System for COVID-19 Cure or Vaccine

Sir,

I was watching you on CNN today and saw they CDC is attempting to look at Plaquenil and thought they mentioned something on immunoglobulins as well. I have already wrote the CDC and also my Governor, in the state of Michigan.

Five years ago, I was inflicted with horrible symptoms of auto immune disease. It took over two years to actually pin it down, by biopsies. They tried a combination of Plaquenil, Prednisone and Methotrexate, to bring down my immune system and treat my symptoms. Those medications did not even affect my immune system negatively.

In 2017, I was diagnosed with Microscopic Polyangiitis (MPA), based on clinical diagnosis and punch biopsies. Since then, I have developed over 25 other illnesses or conditions, to include Schamberg's Disease, Bronchiectasis and Leukocytoclastic Vasculitis. For years, I have been on immuno-suppressive medications to include the following: Rituximab Infusions since Oct 2017; Methotrexate, since 2015; Prednisone, since 2015; Plaquenil for 1.5 years; Methylprednisilone Infusions, for several years; IVigs, for approximately six months, (one six hour infusion, a day, for five days, monthly). So, probably close to 30 infusions of IVigs. These medications did not even affect my high immune system. My disease is still full force and doctors are in the process of investigating more illnesses to include possible mini strokes, hearing issues and speech pathology, for my vocal cord issues.

My bloodwork such as CBC, Comprehensive Metabolic Panel, ESR and CRP, are done every weeks. My bloodwork is perfect and no sign that the immuno-suppressive medications are bringing it down, and my symptoms and diseases are not suppressing. Most if not all my illnesses in the last five years are related somehow to my MPA disease or to my over active immune system.

If Auto immune diseases are a reaction to an over active immune system, and I am not suppressing with all this treatment, does it not mean that my immune system is incredibly high? Can the CDC or medical field do research on my blood? Even if it were a trillion to one chance that I could be of some help with my immune system, it seems worth a try with our current COVID-19 crisis. I am willing to help, if they need to test my blood. Thanks so much for your time.

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/19/2020 1:41:21 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: Hydroxychloroquine supply (>100 million tablets) + other COVID-19 therapeutic updates

As per our conversation

From: Birx, Deborah L. EOP/NSC (b)(6)
Date: March 19, 2020 at 1:39:21 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Hydroxychloroquine supply (>100 million tablets) + other COVID-19 therapeutic updates

From: Kleinerman,Eugenie S [ekleiner@mdanderson.org]
Sent: 3/19/2020 3:17:41 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Potential drug for COVID-19

Good afternoon Steve,

Watching the news conference this morning is prompting this e-mail to bring to your attention a drug for consideration. You did a terrific job by the way.

(b)(5)

I have been encouraged by colleagues to reach out to you to make the suggestion. Happy and honored to discuss further if your team is interested.

Thank you for all that you are doing. Again you looked terrific on TV today and were very reassuring.

God speed and all the Best,

Genie

Eugenie S. Kleinerman, M.D.
Professor, Division of Pediatrics
Professor, Department of Cancer Biology
The Mary V. and John A. Reilly Distinguished Chair
University of Texas M.D. Anderson Cancer Center
1515 Holcombe Boulevard, Unit #853
Houston, Texas 77030

(713) 792-8110
Fax: (713) 563-5407

From: Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]
Sent: 3/19/2020 3:57:52 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: FW: Telecon: Congressman Jeff Fortenberry and Commissioner Hahn
Attachments: Hahn Fortenberry Call 3.19.20.docx

(b)(5)

From: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Sent: Thursday, March 19, 2020 3:54 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Telecon: Congressman Jeff Fortenberry and Commissioner Hahn

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 19, 2020 1:14 PM
To: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Cc: McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Re: Telecon: Congressman Jeff Fortenberry and Commissioner Hahn

(b)(5)

Sent from my iPhone

On Mar 19, 2020, at 1:02 PM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

(b)(5)

-----Original Appointment-----
From: Sheehy, Janice **On Behalf Of** Hahn, Stephen

Sent: Wednesday, March 18, 2020 4:13 PM
To: Hahn, Stephen; McBride, Maren; Karas Gross; Klimczak, Katherine; Nguyen, Michael A.; Tantillo, Andrew; Keagan Lenihan; Anderson, Erika; Colin Rom (Colin.Rom@fda.hhs.gov); Frank Olivarria
Subject: Telecon: Congressman Jeff Fortenberry and Commissioner Hahn
When: Thursday, March 19, 2020 4:30 PM-4:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-888-913-9943,,, (b)(6) (Rep. Fortenberry will call Frank) (Frank will connect the lines)

Please be sure to dial-in **at least 5 minutes** prior to the call's scheduled start time and **mute your phone**. Thanks!

From: y rodriguez [(b)(6)]
Sent: 3/19/2020 4:00:11 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: hernandezr@nyassembly.gov; kpowers@council.nyc.gov; letters@washpost.com; fkhan@nypost.com
Subject: Fw: letter
Attachments: Alfa_2b_2020.docx

Dear Commissioner Hahn,

(b)(5)

Please see our letter attached.

Thank you.

100 United States Citizens for alfa 2-b

From: Erhardt, Paul W. [Paul.Erhardt@utoledo.edu]
Sent: 3/19/2020 4:13:58 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: FW: Repurposing Drugs for COVID-19

Importance: High

Commissioner Hahn or an Administrative Assistant,

Any suggestions for moving this forward? See 'bounce' below? Or if Dr. Hahn is already intending to be responsive to this topic as he did indeed receive the same email, then perhaps no need to also catch Dr. Woodstock?

Thanks,

Paul Erhardt, PhD
Distinguished University Professor Emeritus
Former Director UT Ctr. for Drug Design & Development
Inductee ACS Med Chem (MEDI) Hall of Fame
Chemistry inventor esmolol

From: postmaster@fda.hhs.gov <postmaster@fda.hhs.gov>
Sent: Thursday, March 19, 2020 3:21 PM
To: Erhardt, Paul W.
Subject: Undeliverable: Repurposing Drugs for COVID-19

Delivery has failed to these recipients or groups:

'janet.woodstock@fda.hhs.gov' (janet.woodstock@fda.hhs.gov)
The email address you entered couldn't be found. Please check the recipient's email address and try to resend the message. If the problem continues, please contact your email admin.

Diagnostic information for administrators:

Generating server: FDSWV30901.fda.gov

janet.woodstock@fda.hhs.gov
Remote Server returned '550 5.1.10 RESOLVER.ADR.RecipientNotFound; Recipient not found by SMTP address lookup'

Original message headers:

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Received: from FDSWV09480.fda.gov (10.168.16.139) by FDSWV30901.fda.gov
 (10.185.43.41) with Microsoft SMTP Server (version=TLS1_2,
 cipher=TLS_ECDHE_RSA_WITH_AES_256_CBC_SHA384_P256) id 15.1.1913.5; Thu, 19
 Mar 2020 15:21:06 -0400
Received: from fda-ifw-00.fda.gov (10.168.18.7) by FDSWV09480.fda.gov
 (10.168.17.130) with Microsoft SMTP Server (version=TLS1_2,
 cipher=TLS_ECDHE_RSA_WITH_AES_256_CBC_SHA384_P256) id 15.1.1913.5 via
 Frontend Transport; Thu, 19 Mar 2020 15:21:06 -0400
X-SBRS: 5.1
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Received: from ipss1-host165.is1e1.is.centurylink.net ([65.153.203.165])
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  by fda-ifw-00.fda.gov with ESMTP; 19 Mar 2020 15:21:06 -0400
Received: from fda-ifw-00.fda.gov (unknown [150.148.6.135])
        by ipssl-host165.islel.is.centurylink.net (Postfix) with ESMTP id 74F24240000D
        for <janet.woodstock@fda.hhs.gov>; Thu, 19 Mar 2020 19:21:06 +0000 (GMT)
Authentication-Results: fda-ifw-00.fda.gov; spf=None smtp.pra=Paul.Erhardt@utoledo.edu;
spf=Pass smtp.mailfrom=Paul.Erhardt@utoledo.edu; spf=None smtp.helo=postmaster@mx0a-
00292601.pphosted.com; dkim=pass (signature verified) header.i=@utoledo.edu; dmarc=pass
(p=none dis=none) d=utoledo.edu
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CC: 'Chuck Brunicardi' <cbrunicardi@gmail.com>, "Liu, Shi-He"
        <Shi-He.Liu@UToledo.edu>, "Nemunaitis, John J."
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From: jerrycuttler@r (b)(6)
Sent: 3/19/2020 6:05:56 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: James Welsh (b)(6)
Subject: Potential remedy for COVID-19 disease; 0.5 Gy chest X-ray
Attachments: Calabrese-Dhawan-2013_Radiotherapy treatment of pneumonia.pdf

Importance: High

Dr. Stephen Hahn
Commissioner of FDA
United States Department of Health and Human Services
Silver Spring, MD, 20993

Dear Dr. Hahn

I urge you to consider a chest X-ray treatment of about 50 rad or 0.5 Gy. Since the 1920s, it was an effective remedy for a wide range of inflammatory and infectious diseases, including various types of pneumonia.[1] Therapeutic X-ray exposures were phased out in the mid-1940s when pharmaceutical remedies became available and were adopted as the preferred method of treatment. Such remedies are not yet available for COVID-19, so I urge you to consider using radiotherapy---an old, proven treatment for diseases that produce lung inflammation. One exposure to ionizing radiation is expected to induce an anti-inflammatory phenotype that would provide relief within a few hours. A cure of unresolved pneumonia is usually observed within several days of the treatment.[2] Low doses of ionizing radiation upregulate innate adaptive protection systems, for application in many medical therapies.[3]

The attached review of many old studies indicates a high cure rate.[2] Table 1 shows 863 cases treated and 717 cases cured---a rate of 83%.[2]

(b)(4)

If the investigators recommend this therapy for curing COVID-19, it could be introduced quickly, since appropriate radiation devices are already available in most medical centers.

Sincerely

Jerry M. Cuttler, DSc

(b)(6)

References:

1. Calabrese EJ, Dhawan G, Kapoor R, Kozumbo WJ. Radiotherapy treatment of human inflammatory diseases and conditions: optimal dose. *Hum Exp Toxicol*. 2019;38(8):888-898.

2. Calabrese EJ, Dhawan G. How radiotherapy was historically used to treat pneumonia: could it be useful today? *Yale J Biol Med*. 2013;86:555-570.
3. Cuttler JM. Application of low doses of ionizing radiation in medical therapies. *Dose Response*. 2020;18(1):1-17.

From: Kimberly, Brad [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08BC909ED76D49868A5FF92C3C70FB72-BRADLEY.KIM]
Sent: 3/19/2020 7:39:38 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: RE: TWEETS for REVIEW: Blood Donations // Therapuetics // Hand Sanitizer

Good evening… updating to include additional topics for your review.

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell (b)(6)
brad.kimberly@fda.hhs.gov

From: Kimberly, Brad
Sent: Thursday, March 19, 2020 4:52 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: TWEETS for REVIEW: Blood Donations Statement

Good evening… here are some tweets for your review on the blood donations. Thanks! --Brad

==

Blood Donations Statement
Thread

1. Every two seconds in this country, a patient needs a blood transfusion. At this time, the number of blood donations has been dramatically reduced due to social distancing and the cancellation of blood drives as a result of the #COVID19 pandemic. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-blood-donations **[GRAPHIC]**

2. We fully support @POTUS' Coronavirus Guidelines for America, which includes recommendations to avoid social gatherings & practicing good hygiene, like hand washing. https://www.whitehouse.gov/articles/15-days-slow-spread/

3. We also recognize that maintaining adequate levels of our nation's blood supply is critical. To ensure that blood is available to those who need it most, it is vital for healthy individuals who are able to donate blood to take the time to do so.

4. Donating blood is safe & takes only a little time. Blood donation centers are taking steps to keep staff & donors safe, & using additional social distancing precautions. If you are interested in donating, you can make an appointment so you don't have to wait in line.

5. If you are interested in donating blood, you can find a local blood collection site and schedule an appointment here: https://americasblood.org/for-donors/find-a-blood-center/

Therapeutics Update Tweets

Thread 1

1. FDA is working closely with partners across the U.S. government & regulated industry to expedite the development & availability of medical products to prevent & treat #COVID19, including repurposing existing therapies that may help treat #COVID19 patients https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

2. While there are no FDA-approved therapeutics or drugs to treat, cure, or prevent #COVID19, there are several FDA-approved treatments that may help ease symptoms from a supportive care perspective.

3. FDA continues to work with interested sponsors to help expedite any additional clinical trials for #COVID19 medical countermeasures that may be appropriate. We are able to, and have been, turning around requests very quickly to assist in initiating clinical trials.

4. For example, last month, @NIH began a randomized controlled trial with the investigational antiviral drug remdesivir. Through its expanded access program, FDA has also granted emergency use of this product to about 250 patients. https://www.niaid.nih.gov/news-events/nih-clinical-trial-remdesivir-treat-covid-19-begins

5. Additionally, a randomized controlled trial of the antiviral drug sarilumab, an antibody to the IL-6 receptor is underway. IL-6 receptor inhibitors are thought to be potentially helpful in reducing lung information & improving lung function in #COVID19 patients.

6. There's also interest in evaluating whether therapies, such as convalescent plasma & hyperimmune globulin—antibody-rich blood products that are taken from blood donated by people who have recovered from the virus—could shorten the length, or lessen the severity, of the illness.

7. Facilitating the ultimate widespread use & availability of safe & effective #COVID19 medical countermeasures is critical for many reasons, including that reducing the severity & duration of symptoms could help lessen the burden on medical personnel, equipment & facilities.

Thread 2

1. FDA is working with government & academic partners to investigate the drug chloroquine for possible use in patients with mild to moderate #COVID19 to potentially reduce symptom duration, as well as viral shedding, which can help prevent its spread. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments

2. Chloroquine is a drug that is already approved to treat malaria, lupus, & rheumatoid arthritis. Studies are underway to evaluate its efficacy in combatting #COVID19.

3. We are urgently working to identify prevention & treatment options for #COVID19 – yet we also must ensure products are effective so as not to risk treating patients with a product that might not work when they could have pursued more appropriate treatments.

4. At the same time, we will engage with domestic manufacturers to ramp up production of chloroquine to mitigate any potential supply chain pressures.

5. If clinical data suggests chloroquine may be promising in treating #COVID19, we know there will be increased demand for it, & must take all steps to ensure chloroquine remains available for patients who take it to treat severe & life-threatening illnesses.

Thread 3

1. While we work to facilitate the development of #COVID19 treatment options, FDA is also working with interagency partners, product developers, & international public health organizations to expedite vaccine development to the greatest extent possible. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments

2. This week, @NIH started a phase 1 clinical trial to test the safety of an investigational vaccine for #COVID19. FDA intends to use all available regulatory flexibility to ensure efficient & timely development of a #COVID19 vaccine. https://www.niaid.nih.gov/news-events/nih-clinical-trial-investigational-vaccine-covid-19-begins

Individual Tweets (Non-Thread)

1. FDA continues its work with the public & private sectors to facilitate the availability of potentially safe & effective life-saving drugs to patients who are in need of treatment, including those infected with #COVID19 https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**
2. FDA continues to demonstrate our commitment to responding swiftly to the #COVID19 pandemic & providing regulatory flexibility & relief where it is needed for medical products designed to diagnose, treat & mitigate #COVID19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**
3. FDA is working with government & academic partners that are investigating the off-label use of the FDA-approved malaria drug chloroquine to determine whether it can be used to treat patients with mild to moderate #COVID19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**
4. FDA understands the urgency with which we are all seeking prevention & treatment options for #COVID19. We are using all available regulatory flexibility to facilitate the development of therapies & vaccines for the prevention & treatment of #COVID19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

Hand Sanitizer
Thread

1. As part of FDA's ongoing commitment to address the #COVID19 pandemic, the agency issued two guidance documents on the production of alcohol-based hand sanitizers to boost supply and protect Americans' health during the public health emergency. **[LINK TO PR] [GRAPHIC]**

2. Many manufacturers make hand sanitizers & several have indicated they are working to increase supply. We will continue to work with manufacturers, compounders, state boards of pharmacy & the public to increase the supply of alcohol-based hand sanitizer available to Americans.

Individual Tweets (Non-Thread)

1. FDA is providing guidance on the production of alcohol-based hand sanitizer during the #COVID19 public health emergency: **[LINK TO PR]**

2. As part of FDA's ongoing commitment to address the #COVID19 pandemic, the agency issued two guidance documents on the production of certain alcohol-based hand sanitizer products. **[LINK TO PR]**

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: (b)(6)
brad.kimberly@fda.hhs.gov

From: kenneth locke [(b)(6)]
Sent: 3/19/2020 7:46:16 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione];
(b)(6)
CC: Xin Li [lixin@Sphbio.com]
Subject: Clinical trial data available for Hydroxychloroquine & Chloroquine from controlled clinical testing in China

Dear Drs. Hahn and Fauci:

I am the Chief Scientific Officer for Shanghai Pharma Biotherapeutics USA Inc. (SPHBio), a wholly owned subsidiary of Shanghai Pharma Holding (SPH), the second largest pharmaceutical company in China. SPH has manufactured and tested hydroxychloroquine and chloroquine as treatments for COVID-19 under a controlled clinical trial protocol across hospitals in China. The clinical trial data is now available and support the safety and efficacy of these agents against COVID-19. In addition, SPH manufactures these agents under cGMP by the millions of tablets. I am looking for the best way to get this information to the FDA, so that these drugs can be made available for the treatment of COVID-19 in the U.S. This IS the "game changer" that the President is looking for.

Best regards,

Kenneth W. Locke, Ph.D.

Kenneth W. Locke, Ph.D.
Chief Scientific Officer
Shanghai Pharma Biotherapeutics USA Inc.
3545 John Hopkins Ct., Ste 160
San Diego, CA 92121
(b)(6)

From: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Sent: 3/19/2020 7:50:19 PM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]

Subject: Media Telecon: Bernie and Sid in the Morning in NYC
Location: Call In: **(b)(6)**

Start: 3/20/2020 7:05:00 AM
End: 3/20/2020 7:20:00 AM
Show Time As: Busy

Required Attendees: Caliguiri, Laura; Caccomo, Stephanie

For all of these interviews, you will have to call in. Stephanie will be calling in separately on a back-up line. So she will be listening to his interview with you.

Here's the schedule:

Stephanie will call Dr. Hahn at 7:00am for a quick touch point and go over the interviews.

1. **By 7:05**, you will call into Bernie and Sid in the Morning in NYC, producer is Jill Vitale. Live broadcast. **Please call:** **(b)(6)** (backup line is **(b)(6)** just in case). You will tape from 7:08 to 7:18. Here are the proposed questions I sent them:
What does the landscape look like for drugs and other treatments to help patients with coronavirus?
What about vaccine development? Can a vaccine be available right away?
What steps have you taken to make sure there are diagnostic tests in the field? Have you worked with industry to promote that test development?

2. **By 7:35,** call into Pensacola Morning News with Andrew McKay. Live broadcast. **Please call** **(b)(6)** **(b)(6)** You will tape from 7:36 to 7:45am
Producer agreed to discuss therapeutics

3. **By 7:50,** call into NPR national with David Green or Rachel Martin. Taped broadcast. **Please call** **(b)(6)** **(b)(6)** Taped from 7:50-8am
Interview on coronavirus efforts, potential for therapeutics/vaccines, etc.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/19/2020 8:25:38 PM
To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: RE: TWEETS for REVIEW: Blood Donations // Therapuetics // Hand Sanitizer // EUA

Approved - all

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Date: March 19, 2020 at 8:21:12 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: Blood Donations // Therapuetics // Hand Sanitizer // EUA

Adding one final one to the pile. But this will be it for the night. Thanks! –Brad

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: (b)(6)
brad.kimberly@fda.hhs.gov

From: Kimberly, Brad
Sent: Thursday, March 19, 2020 4:52 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah

<Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: TWEETS for REVIEW: Blood Donations Statement

Good evening… here are some tweets for your review on the blood donations. Thanks! --Brad

==

EUA Tweets
Thread
1. Today, FDA issued diagnostic EUAs to GenMark Diagnostics, Inc. for its ePlex SARS-CoV-2 Test and Diasorin Molecular LLC for its Simplexa COVID-19 Direct https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd **[EUA GRAPHIC]**
2. Test developers that have questions about the EUA process can contact our toll-free line 24 hours a day at 1-888-INFO-FDA (choose option *) or visit our #COVID19 diagnostic testing FAQs: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

Blood Donations Statement
Thread
1. Every two seconds in this country, a patient needs a blood transfusion. At this time, the number of blood donations has been dramatically reduced due to social distancing and the cancellation of blood drives as a result of the #COVID19 pandemic. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-blood-donations **[GRAPHIC]**

2. We fully support @POTUS' Coronavirus Guidelines for America, which includes recommendations to avoid social gatherings & practicing good hygiene, like hand washing. https://www.whitehouse.gov/articles/15-days-slow-spread/

3. We also recognize that maintaining adequate levels of our nation's blood supply is critical. To ensure that blood is available to those who need it most, it is vital for healthy individuals who are able to donate blood to take the time to do so.

4. Donating blood is safe & takes only a little time. Blood donation centers are taking steps to keep staff & donors safe, & using additional social distancing precautions. If you are interested in donating, you can make an appointment so you don't have to wait in line.

5. If you are interested in donating blood, you can find a local blood collection site and schedule an appointment here: https://americasblood.org/for-donors/find-a-blood-center/

Therapeutics Update Tweets
Thread 1
1. FDA is working closely with partners across the U.S. government & regulated industry to expedite the development & availability of medical products to prevent & treat #COVID19, including repurposing existing therapies that may help treat #COVID19 patients https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

2. While there are no FDA-approved therapeutics or drugs to treat, cure, or prevent #COVID19, there are several FDA-approved treatments that may help ease symptoms from a supportive care perspective.

3. FDA continues to work with interested sponsors to help expedite any additional clinical trials for #COVID19 medical countermeasures that may be appropriate. We are able to, and have been, turning around requests very quickly to assist in initiating clinical trials.

4. For example, last month, @NIH began a randomized controlled trial with the investigational antiviral drug remdesivir. Through its expanded access program, FDA has also granted emergency use of this product to about 250 patients. https://www.niaid.nih.gov/news-events/nih-clinical-trial-remdesivir-treat-covid-19-begins

5. Additionally, a randomized controlled trial of the antiviral drug sarilumab, an antibody to the IL-6 receptor is underway. IL-6 receptor inhibitors are thought to be potentially helpful in reducing lung information & improving lung function in #COVID19 patients.

6. There's also interest in evaluating whether therapies, such as convalescent plasma & hyperimmune globulin—antibody-rich blood products that are taken from blood donated by people who have recovered from the virus—could shorten the length, or lessen the severity, of the illness.

7. Facilitating the ultimate widespread use & availability of safe & effective #COVID19 medical countermeasures is critical for many reasons, including that reducing the severity & duration of symptoms could help lessen the burden on medical personnel, equipment & facilities.

Thread 2

1. FDA is working with government & academic partners to investigate the drug chloroquine for possible use in patients with mild to moderate #COVID19 to potentially reduce symptom duration, as well as viral shedding, which can help prevent its spread. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments

2. Chloroquine is a drug that is already approved to treat malaria, lupus, & rheumatoid arthritis. Studies are underway to evaluate its efficacy in combatting #COVID19.

3. We are urgently working to identify prevention & treatment options for #COVID19 – yet we also must ensure products are effective so as not to risk treating patients with a product that might not work when they could have pursued more appropriate treatments.

4. At the same time, we will engage with domestic manufacturers to ramp up production of chloroquine to mitigate any potential supply chain pressures.

5. If clinical data suggests chloroquine may be promising in treating #COVID19, we know there will be increased demand for it, & must take all steps to ensure chloroquine remains available for patients who take it to treat severe & life-threatening illnesses.

Thread 3

1. While we work to facilitate the development of #COVID19 treatment options, FDA is also working with interagency partners, product developers, & international public health organizations to expedite vaccine development to the greatest extent possible. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments

2. This week, @NIH started a phase 1 clinical trial to test the safety of an investigational vaccine for #COVID19. FDA intends to use all available regulatory flexibility to ensure efficient & timely development of a #COVID19 vaccine. https://www.niaid.nih.gov/news-events/nih-clinical-trial-investigational-vaccine-covid-19-begins

Individual Tweets (Non-Thread)

1. FDA continues its work with the public & private sectors to facilitate the availability of potentially safe & effective life-saving drugs to patients who are in need of treatment, including those infected with #COVID19 https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

2. FDA continues to demonstrate our commitment to responding swiftly to the #COVID19 pandemic & providing regulatory flexibility & relief where it is needed for medical products designed to diagnose, treat & mitigate #COVID19.

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

3. FDA is working with government & academic partners that are investigating the off-label use of the FDA-approved malaria drug chloroquine to determine whether it can be used to treat patients with mild to moderate #COVID19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

4. FDA understands the urgency with which we are all seeking prevention & treatment options for #COVID19. We are using all available regulatory flexibility to facilitate the development of therapies & vaccines for the prevention & treatment of #COVID19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments **[GRAPHIC]**

Hand Sanitizer
Thread

1. As part of FDA's ongoing commitment to address the #COVID19 pandemic, the agency issued two guidance documents on the production of alcohol-based hand sanitizers to boost supply and protect Americans' health during the public health emergency. **[LINK TO PR] [GRAPHIC]**

2. Many manufacturers make hand sanitizers & several have indicated they are working to increase supply. We will continue to work with manufacturers, compounders, state boards of pharmacy & the public to increase the supply of alcohol-based hand sanitizer available to Americans.

Individual Tweets (Non-Thread)

1. FDA is providing guidance on the production of alcohol-based hand sanitizer during the #COVID19 public health emergency: **[LINK TO PR]**

2. As part of FDA's ongoing commitment to address the #COVID19 pandemic, the agency issued two guidance documents on the production of certain alcohol-based hand sanitizer products. **[LINK TO PR]**

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
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Tel 240-402-1002 | Cell: (b)(6)
brad.kimberly@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/19/2020 8:28:13 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Media interviews tomorrow

Sounds good

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 19, 2020 at 7:36:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: Media interviews tomorrow

Looks like for tomorrow am.

Sent from my iPhone

Begin forwarded message:

From: "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>
Date: March 19, 2020 at 7:35:29 PM EDT
To: "Olivarria, Frank" <Frank.Olivarria@fda.hhs.gov>, "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Copeland, Jakea" <Jakea.Copeland@fda.hhs.gov>
Cc: "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>, "Rebello, Heidi" <Heidi.Rebello@fda.hhs.gov>
Subject: Media interviews tomorrow

Plan for tomorrow:

For all of these interviews, Dr. Hahn will have to call in. I will be calling in separately on a back-up line. So I will be listening to his interview with him.

Here's the schedule:

I will call Dr. Hahn at 7:00am for a quick touch point and go over the interviews.

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What steps have you taken to make sure there are diagnostic tests in the field? Have you worked with industry to promote that test development?

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Producer agreed to discuss therapeutics

3. By 7:50, call into NPR national with David Green or Rachel Martin. Taped broadcast. Please call (b)(6) (b)(6) Taped from 7:50-8am
Interview on coronavirus efforts, potential for therapeutics/vaccines, etc.

Attaching topline messages for Dr. Hahn to use. Plus final press release issued today

Stephanie Caccomo
Press Officer

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

From: Duncan Knowles [(b)(6)]
Sent: 3/19/2020 9:23:06 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: A workable idea for a vaccine for coronavirus.

Dear Dr. Hahn,

You have asked for ideas to stop coronavirus. Here is one that has every chance of working and has a science background:

A few years back, a world famous Canadian virologist, Dr. Jack Konowalchuk, worked with his son Dr. Tom Konowalchuk in Oregon to unveil a previously unknown antiviral compound from a natural source. They succeeded.

In vitro the compound inactivates every virus it is tested against, including SARS, a representative of the coronavirus family. It is nontoxic. It not only binds the virus and stops it from attaching to the target cell. Over a short time it causes the virus particles to clump and break apart. The Konowalchuk's theorized this new compound could be effective as a vaccine when mixed with the inactivated virus.

Because Avian Flu H5N1 was a huge concern at the time, they paid to have a 400 animal vaccine test performed at the Institute for Antiviral Research in Utah.

A successful vaccine
In that study half the mice were vaccinated with a mixture of this compound combined with completely inactivated H5N1. No adjuvants, preservatives, or other chemicals were added. Then vaccinated and unvaccinated animals were exposed to a lethal dose of H5N1.

All the properly vaccinated animals lived and thrived. They showed no effect of being exposed to the deadly H5N1 virus. But practically all the unvaccinated animals died from their exposure to H5N1.

Real promise against coronavirus
The coronavirus family is one of the viruses this compound inactivates in vitro. Dr. Hahn, we feel it is definitely worth testing this vaccine and treatment approach in an animal model against COVID-19.

Why is this unique?
What's unique here is that this new compound has never been isolated before. Its ability to bind with a virus and stop it from attacking cells is significant. And in a matter of minutes, the viral particles begin to break apart. Yet when formulated as a vaccine, it immediately causes the immune system to build full and sufficient defenses to repel the real virus when it comes.

This compound is so unique the U.S. Patent Office has given it a patent as well as a patent on the process of producing it.

Situation
Dr. Jack Konowalchuk passed away and his son is a practicing community doctor in Oregon. He does not have the funds to shepherd this potentially life-saving approach through the approval process. He needs your help.

The request

Testing ASAP in an animal model against COVID-19 is definitely called for. Dr. Konowalchuk is happy to freely supply all the compound you need for testing. We respectfully request that you authorize and initiate this testing process.

The upside potential here is that this approach could become the platform for a universal vaccine. If that proves out, wouldn't it be a blessing to have when the next virus begins to sweep the globe?

Respectfully,

Duncan Knowles
Family friend

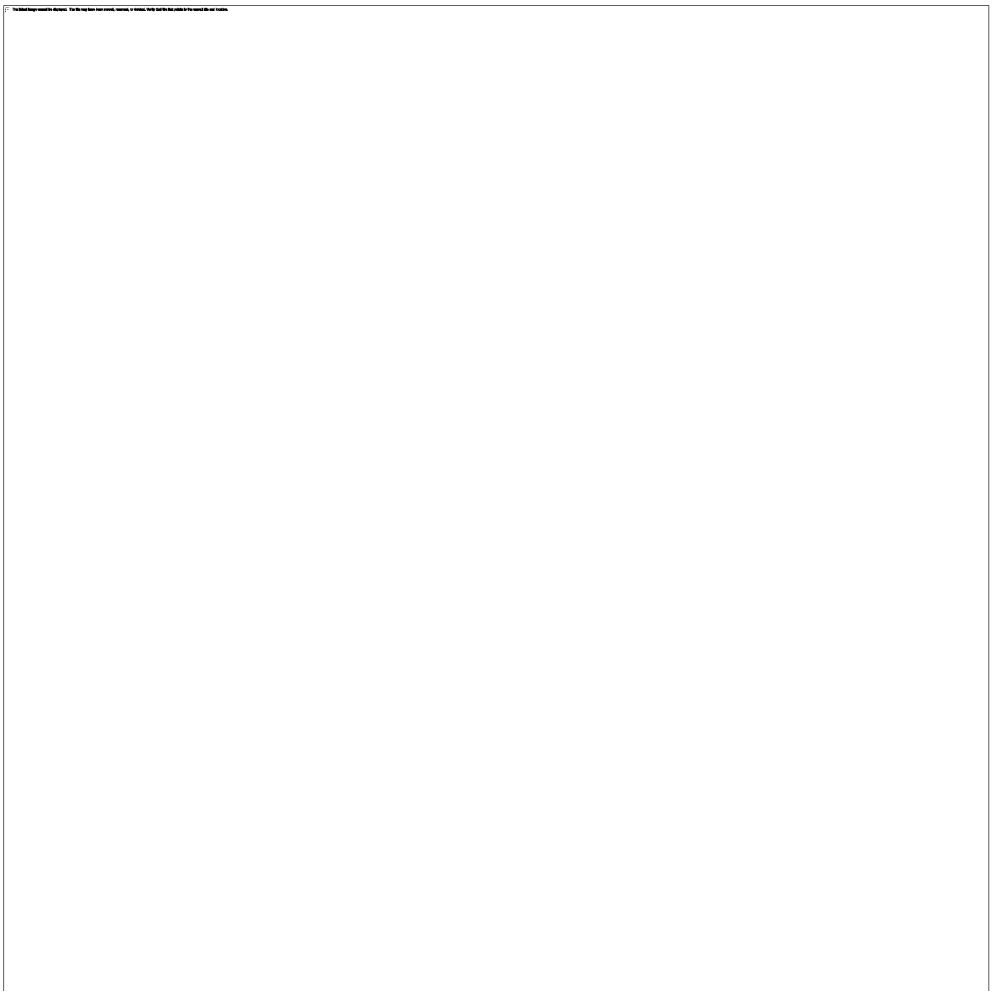
(b)(6) cell
home office

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 5:50:43 AM
To: Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]
Subject: Fwd: The trillion-dollar coronavirus negotiation kicks off — The new coronavirus 'star': Surgeon General Jerome Adams — Frontline supply shortages abound

Indeed, our new star. That is most certainly true.
Well done.
S

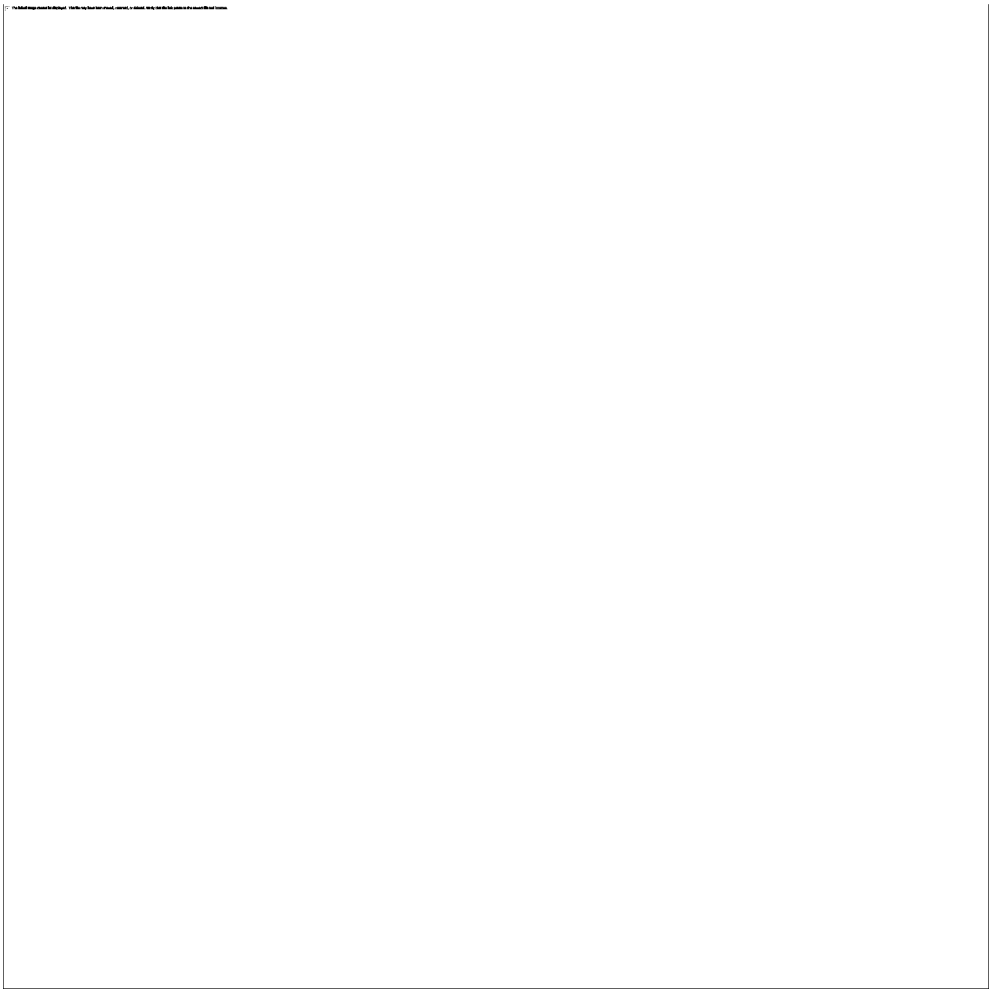
From: POLITICO Pro's Pulse <politicoemail@politicopro.com>
Date: March 20, 2020 at 5:48:47 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: The trillion-dollar coronavirus negotiation kicks off — The new coronavirus 'star': Surgeon General Jerome Adams — Frontline supply shortages abound

Mar 20, 2020 View in browser



BY **ADAM CANCRYN** AND **DAN DIAMOND**

Presented by



QUICK FIX

— The Senate GOP unveiled its trillion-dollar coronavirus proposal, kicking off the highest-stakes health care lobbying frenzy in recent memory.

— The coronavirus outbreak has made a star out of Surgeon General Jerome Adams, who is newly visible after spending most of the Trump administration on the sidelines.

— Health care workers are confronting severe shortages of protective equipment, despite White House assurances that supplies are on their way.

WELCOME TO FRIDAY PULSE — And thanks for being part of the PULSE community. Hang in there, be good to each other and feel free to reach out any time: acancryn@politico.com and ddiamond@politico.com.

Sign up for POLITICO Nightly: Coronavirus Special Edition, your daily update on how the illness is affecting politics, markets, public health and more.

DRIVING THE DAY

THE TRILLION-DOLLAR CORONAVIRUS NEGOTIATION KICKS OFF — Senate Republicans made their opening offer on a trillion-dollar coronavirus aid package Wednesday night, paving the way for the high-speed negotiation likely to consume Washington for the next several days.

The proposal's centerpiece is a direct payment to qualified Americans and roughly $300 billion in federally guaranteed loans for small businesses. But there's plenty for this town's health care interests to jockey over — setting up perhaps the highest-stakes lobbying frenzy in recent memory. A quick rundown:

— Hospitals and health centers get a boost. The legislation aids hospitals by temporarily freezing the sequester's Medicare payment cut, along with imposing a separate 15 percent Medicare rate bump for coronavirus patients. Community health centers would receive $1.32 billion to fund their care for vulnerable patients.

— Health insurers would need to cover coronavirus vaccines.

The pre-emptive requirement applies to any vaccines and preventive measures that could be developed down the road.

— Telehealth access gets easier. The proposal temporarily allows Medicare patients to virtually consult with doctors even though they don't have a pre-existing relationship, lifting a major telehealth restriction.

— But it didn't grant some of the bigger wishes. Commercial labs didn't get the $5 billion fund they'd pushed for to support elevated expenses, or a guarantee that patients who show up for drive-through testing will be paid for. The bill also doesn't extend direct financial assistance to hospitals.

WHAT HOSPITALS WANT: $100 BILLION TO START — That's the big ask from the American Hospital Association, American Medical Association and American Nurses Association, ahead of what providers expect will be a massive surge of coronavirus patients.

Health systems are already putting off profitable elective surgeries and bracing for a prolonged emergency that will test their capacity, workforce and financial stability, POLITICO's Susannah Luthi, Rachel Roubein and Dan Goldberg report. That's created a moment of solidarity for massive hospital chains whose executives rake in multimillion-dollar salaries and smaller independent community and rural hospitals.

— The industry has an ally in CHUCK SCHUMER. The Senate minority leader is calling for $400 billion to purchase equipment and deal with the swell in patients as part of a proposal he's termed a "Marshall Plan for hospitals."

THE NEW CORONAVIRUS 'STAR': JEROME ADAMS — Surgeon General Jerome Adams has emerged as a key figure in the Trump administration's coronavirus messaging, after being sidelined for much of his time in the government, POLITICO's Dan Diamond reports.

Adams is now a regular on Fox News and other programs and has

routinely flanked Trump at press briefings — where the president called him one of the new "stars" of the administration. But Adams also has made waves in the process of echoing his boss' own questionable claims about the outbreak.

— The surgeon general repeatedly suggested the flu was more of a risk than the coronavirus and once claimed Trump is "healthier" than him. Meanwhile, some of his other warnings have been prescient, including a call for hospitals to cancel elective procedures.

Adams also is a close ally of Vice President Mike Pence, having helped the then-governor fight Indiana's HIV outbreak, and won bipartisan plaudits from officials like Rebekah Gee, the Democrat who served as Louisiana's health secretary until this year and praised Adams' apolitical approach.

— Adams' portfolio had been limited until now. HHS leaders worried the physician would fail to stay on message, four officials said. He also fell out of favor with HHS Secretary Alex Azar, who has preferred to lean on Assistant Secretary for Health Brett Giroir, Adams' boss.

FRONTLINE SUPPLY SHORTAGES ABOUND — Doctors and nurses are confronting severe shortages of masks and other protective equipment despite White House assurances that plenty of supplies are on the way, POLITICO's Alice Miranda Ollstein reports.

The scarcity has forced providers to take to social media with pleas for more gear, and prompted state officials to beg the private sector to donate masks. Even the CDC has been blunt about the situation, telling health workers to reuse masks or construct homemade ones — advice that medical professionals say is dangerous.

— That's a different story than the White House is trying to sell. Pence on Thursday touted the lifting of legal liability for masks not previously approved for hospital use, contending it has "vastly increased the supply of medical masks."

But 500 million masks that the government ordered this week may not be delivered for another year-and-a-half. And Massachusetts lawmakers say they've only gotten 10 percent of the 750,000 masks and other equipment they requested weeks ago. In hard-hit Washington state, there remain shortages despite two shipments from the Strategic National Stockpile.

DO YOU WORK FOR A HOSPITAL? TELL US WHAT YOU SEE — POLITICO is tracking hospital capacity, patient surge and health care workers' ability to obtain protective gear — and how the outbreak is affecting their own health. Tell us about your experience here.

STATES STILL WAITING ON CORONAVIRUS TESTS — States still have no idea where and how fast the coronavirus is spreading, thanks to an ongoing shortage of tests that's persisted for nearly a month, POLITICO's Dan Goldberg, Brianna Ehley and David Lim report.

The federal help that governors sought weeks ago still hasn't arrived, forcing health officials to ration tests and creating backlogs that are delaying results. The shortage comes despite repeated assurances that the administration is ramping up its test capacity, including Trump's

claim Thursday that he was hearing "very good things on the ground."

— Things on the ground are not good, governors say. Private labs are not meeting test demand, and administration promises of supplies and a host of new testing sites have yet to materialize.

"I feel a little like Charlie Brown and Lucy with the football with the federal government," said Illinois Gov. J.B. Pritzker.

IN THE STATES

CALIFORNIA LOCKS DOWN — Gov. Gavin Newsom is ordering California's nearly 40 million residents to stay home, marking the most restrictive mandate yet in response to the outbreak. The order will remain in place indefinitely, preventing Californians from leaving their homes except for essentials, POLITICO's Jeremy B. White reports.

More than one-third of the state's counties had already issued shelter-in-place orders. Newsom warned that 56 percent of residents — roughly 22 million people — could become infected over the next two months if California as a whole does not respond aggressively.

ON THE HILL

SENATORS SOLD STOCK AHEAD OF OUTBREAK — At least three senators dumped millions of dollars in stock after receiving briefings

on the coronavirus but before the market began to collapse.

Sen. Richard Burr sold between $628,000 and $1.7 million of shares while receiving regular intelligence briefings and offering public assurances about the administration's readiness to combat the virus, ProPublica reported. Sen. Kelly Loeffler, meanwhile, went on a selling spree beginning the day she sat in on a private coronavirus briefing.

Loeffler sold seven figures worth of stock across 27 transactions that she and her husband made through mid-February, according to the Daily Beast. One of only two purchases during that period: shares in teleworking software company Citrix.

The New York Times also noted that Sen. Dianne Feinstein — who also sits on the Intelligence Committee — sold stock between Jan. 31 and Feb. 18, while Sen. Jim Inhofe sold shares in several companies on Jan. 27.

— BURR and LOEFFLER are now facing calls to resign from inside and outside the Capitol. Progressive Rep. Alexandria Ocasio-Cortez said the GOP senators' actions were "stomach-churning." And Trump ally Tucker Carlson on his FOX News show urged Burr to explain or "resign from the Senate and face prosecution for insider trading."

— A Burr spokesperson downplayed his stock trading by arguing that the sales came before the market began to show signs of strain, POLITICO's Kyle Cheney reports — which, as many people subsequently noted, is the entire point. Loeffler late Thursday claimed that she does not have control over changes made to her investment portfolio.

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IN CASE YOU MISSED IT

MILKEN INSTITUTE LAUNCHES CORONAVIRUS TRACKER — The think tank Wednesday launched the resource to track therapies and vaccines for the disease. The tracker includes information on the organization developing the medical product, funding sources, anticipated timing and related media coverage.

STUDY: MOST HOSPITAL BEDS ALREADY TAKEN — Nearly two-thirds of the nation's 728,000 hospital beds may already be occupied, the Urban Institute projects. The organization's analysis found that only 36 percent of beds were unoccupied on a typical day in 2018, shrinking availability in the U.S. to just 0.8 unoccupied beds per 1,000 people.

WHAT WE'RE READING

The FDA is not budging from its ban on gay men donating blood, despite the administration's urgent calls for blood donations amid the coronavirus crisis, the Washington Blade's Chris Johnson reports.

On their new "Pandemic" podcast, Celine Gounder and Ron Klain quiz ex-CMS acting administrator Andy Slavitt about the state of the health system as the coronavirus threat bears down. Dan also popped on to talk about POLITICO's recent reporting.

There's no evidence that taking ibuprofen worsens coronavirus symptoms, BuzzFeed's Stephanie M. Lee reports.

The search for a coronavirus cure has become a competition between countries, the New York Times' David Sanger, David Kirkpatrick, Sui-Lee Wee and Katrin Bennhold write.

The Atlantic's Amanda Mull writes about a side effect of the outbreak: "plague dread."

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Subject: Re: SWABS

(b)(5)

Steve

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Date: March 19, 2020 at 5:40:08 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: SWABS

(b)(5)

Brett P. Giroir, MD
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200 Independence Avenue, SW
Washington, DC 20201
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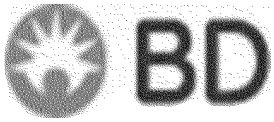
From: Dave Hickey <Dave Hickey@bd.com>
Date: March 19, 2020 at 2:54:51 PM EDT
To: Lauren Silvis (b)(6)
Subject: FW: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

Lauren – FYI – our CEO now reaching out to head of agency directly



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From: Tom Polen <tom polen@bd.com>
Sent: Thursday, March 19, 2020 2:48 PM
To: Elizabeth Woody <elizabeth woody@bd.com>; Dave Hickey <Dave Hickey@bd.com>
Subject: FW: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

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From: Tom Polen
Sent: Thursday, March 19, 2020 2:47 PM
To: 'SH1@fda.hhs.gov' <SH1@fda.hhs.gov>; 'Keagan.Lenihan@fda.hhs.gov' <Keagan.Lenihan@fda.hhs.gov>
Subject: Your Support in Validation of Nasal Swabs & Addressing Testing Bottlenecks - White House Follow-up

Steve,

(b)(5)

Please feel free to call me directly with any questions/concerns. My cell is (b)(6)

Tom

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Sent: 3/20/2020 9:49:04 AM
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CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77bfb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]; Harper, Victor G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d572fe7d36f44ffe86101e5cbef9c957-HHS-Victor.]; Strom, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2f4d6abdbc4eec80dfd3aed4998ab8-HHS-John.St]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; Nestor, Johanna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7300c323111244b98d81be8858dd2c2d-HHS-Johanna]; Twomey, John K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dabd734e611a472d826cd89d9bc4a352-HHS-John.Tw]

Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: FOUO - DRAFT - SNS Vents Distribution to States Options-vFINAL clean.docx; Ventilators Allocation Strategy DLG 20Mar2020.pptx; COVID-19-DLG-Summary of Conclusions-20200318-FINAL-APPROVED.docx; COVID-19- DLG Agenda-20200320-FINAL-APPROVED.docx
Location: 202-774-2300,, (b)(6)

Start: 3/20/2020 3:00:00 PM
End: 3/20/2020 4:00:00 PM
Show Time As: Free

Recurrence: (none)

Update: The attached documents include (1) the Courses of Action for Strategic National Stockpile Ventilator Allocation paper; (2) The agenda for today's DLG; and (3) The presentation to be displayed during today's DLG. Also attached is the Summary of Conclusions from our DLG on Wednesday, March 18.

We ask that you review the paper prior to the start of the meeting.

We also encourage senior leaders to call-in or designate representatives with your full authority. Today's discussion of Allocation Strategy for SNS-held Ventilators will produce recommendations to be forwarded to the Task Force, so we want input from leadership across HHS.

Disaster Leadership Group Team
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning, and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (HHS)
DLGDesk@hhs.gov | www.phe.gov

Dear Disaster Leadership Group (DLG) Members:

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

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

Conference Line

Conference Number: (202) 774-2300
Meeting Access Code: (b)(6)
WebEx: https://meetingserver.hhs.gov/orion/joinmeeting.do?MTID= (b)(6)

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

Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) 245-0719
Daniel.Dodgen@HHS.Gov | www.phe.gov

From: Kirk Kimmerling [kirkkimmerling@fitebac.com]
Sent: 3/20/2020 11:25:50 AM
To: secretary@hhs.gov; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
CC: FDA Office of Media Affairs [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba68dcacb6414bfcb486f469c04bc5f1-FDAOfficeof]; John Sharkey [johnsharkey@fitebac.com]
Subject: FiteBac / CDC Correspondence

FiteBac Letter to CDC

Centers for Disease Control 1600 Clifton Road NE Atlanta GA 30329

HHS Secretary Alex Azar, FDA CDC Director Robert R. Redfield,
FDA Director Stephen Hahn

The purpose of this letter is to express our deep concern with CDC's
(i) conflicting positions on preferred hand sanitizing methods. At times it appears CDC's position is that hand washing is preferred over the use of alcohol hand sanitizers while at other times CDC appears to imply alcohol is the preferred method for hand sanitization.

(ii) CDCs position stating alcohol-based hand sanitizers with greater than 60% alcohol, regardless of the situation or pathogens of concern (including the current COVID-19 outbreak), are the only hand sanitizers recommended.
There is now general agreement the first, and most important, step in maintaining good hand hygiene is the regular use of soap and water to wash your hands (https://www.cdc.gov/handwashing/when-how-handwashing.html). CDC continues to publicly state a strong preference for alcohol-based OTC hand sanitizers containing at least 60% alcohol over other FDA compliant options for hand sanitization when soap and water are not available.

As CDC is aware, it is the US FDA which is responsible for regulatory oversight of OTC hand sanitizer products within the United States and its' territories. EPA is responsible for oversight of surface sanitizers and other products not intended to be applied directly to humans.

While ethanol, isopropanol and benzylkonium chloride are allowed to be used as active ingredients in FDA compliant OTC hand sanitizers, and all are considered broad spectrum antimicrobials, CDC has routinely shown a preference for recommending alcohol-based hand sanitizers. We suspect this is due to the misperception that, in all cases, alcohols are more efficacious against any and all pathogens. The available literature does not support this blanket assumption as there are several examples in which benzylkonium chloride has been shown to be equivalent, and at times superior, to alcohol against pathogens which are of particular concerns in the context of Hospital Acquired Infections (HAI's).

In the case of the current COVID-19 outbreak, we are unaware of any peer-reviewed work demonstrating efficacy of the FDA allowed OTC hand sanitizing actives, never mind the superiority of alcohol against this virus. What is generally known is both alcohol and benzylkonium chloride have demonstrated efficacy against subsets of 'enveloped' viruses, of which COVID-19 belongs. Thus, we do not agree CDC's stated preference for alcohol-based hand sanitizers is supported by the available literature, as the activity of any of these agents

against COVID-19 is currently unknown.

Medical, religious, occupational and cultural considerations must also be taken into consideration when encouraging populations to focus on hand hygiene, including potential side effects from chronic use of these products.

- The best hand sanitizer for a specific organism is dependent on several factors including, sensitivity of the pathogen to the active, how the active is formulated and its persistence on the skin.
- Benzylkonium chloride has been shown to persist on the skin for an extended period, compared to alcohol which dissipates rapidly following application. Persistence has the potential to inhibit pathogen re-establishment and growth and thus the potential to maintain reduced pathogen levels on the skin over an extended period of time.
- Chronic use of 60%-95% (120 to 190 proof) alcohol-based hand sanitizers is known to negatively impact skin health with a resultant decrease in usage compliance, especially amongst healthcare workers. CDC has acknowledged chronic use of alcohol-based hand sanitizers is a significant contributor to chronic dermatitis. Lack of compliance with clean hand protocols is known to be a significant risk factor for disease transmission.
- Religious, medical, occupational and cultural reasons may prevent portions of the population from using alcohol-based products as part of their regular hand hygiene protocol Alcohols are known to be significantly absorbed through the skin and to also enhance the absorption of other materials. Professionals such as airline pilots, commercial truck drivers, air traffic controllers and many other occupations, where any indication of alcohol impairment can negatively impact careers, have expressed concerns around absorbing detectable levels of alcohol as a result of the frequent and prolong use of alcohol containing hand sanitizers. For some religious denominations, alcohol use of any kind is at a minimum frowned upon, if not outright banned.

Finally, individuals dealing with substance abuse and recovery can have concerns with the presence and use of alcohol containing hand sanitizers around them.

As is clearly apparent from the above discussion, there is no single hand sanitizer active or FDA compliant OTC product which can be recommended for all situations. What is best in any situation is dependent on the pathogen(s) of concern and the needs of the user. What cannot be argued is no matter the situation, use of an FDA compliant OTC hand sanitizer either in place of or as a compliment to soap and water, is universally better than not using one at all.

As was previously stated in this letter, US FDA is solely responsible for regulatory oversight of OTC hand sanitizer products within the United States and its' territories. Applicable FDA monographs currently exist for OTC hand sanitizers intended for both Consumer and Healthcare workers. CDC should already be aware labeling claims are specifically addressed in the monographs and claims of efficacy against, for example, specific viruses are not allowed even when available data demonstrates activity. GoJo Industries, the manufacturer of Purell products, recently received a significant warning letter from FDA pertaining to labeling claims which were outside of those allowed under the monograph, even though the literature suggested efficacy against some of the organisms listed.

It is our strong belief the continuing recommendation by CDC that only alcohol-based hand sanitizers are acceptable for hand sanitization, when soap and water is not available, goes against the available science and the current regulatory position promulgated by FDA in this area and is confusing to both healthcare professionals and the public at large.

One of CDC's key objectives in the area of hand hygiene should be to encourage people to establish good hand hygiene practices and behaviors for a lifetime. Such practices should include the use of FDA monographed and/or approved OTC hand sanitizer products as part of an individual's hand hygiene protocol. CDC should be encouraging people to identify FDA compliant OTC products, containing a broad-spectrum antimicrobial,

which meets their life needs (cultural, religious, medical, occupational etc.) and incorporate these products into their daily routine.

The COVID-19 outbreak offers us once again a teachable moment, with both healthcare workers and the general public, around the need for good hand hygiene practices over a lifetime. AS CDC knows, we can never eliminate transmission risk, we can only reduce it with the implementation of appropriate reduction strategies.

By encouraging people to incorporate FDA compliant OTC hand sanitizers into their hygiene protocols, versus CDC's current position of using either 60% alcohol-based hand sanitizers or nothing at all, we can encourage both the public in general, and healthcare workers in particular, to identify and incorporate a suitable FDA compliant OTC hand sanitizer which they can use for a lifetime. Encouraging this behavior should result in reduced infection rates and therefore should be a long-term focus for the CDC

We would very much would like to meet with the appropriate people at CDC to discuss this issue and therefore request a meeting with CDC to further elaborate our current thinking.

Looking forward to your positive response I remain,

Sincerely,
Kirk Kimmerling, DDS
Founder / Chief Architect FiteBac Technology FiteBacSkinCare.com

CDC Update

Dear All,

We continue to get resistance or inaction at CDC on this issue of upgrading guidelines to reflect the utilization of FDA compliant Hand Sanitizers. We received a call on Monday from Nikki Romanik, assistant to Kyle McGowan, Chief of Staff to the Head of the CDC, Dr. Redfield. She stated she had distributed our email, which was shared with you previously and is attached again for your convenience, for consideration of and feedback to our comments by experts within CDC. We also expressed our continuing concern with CDC's continuing emphasis, when soap and water are not available in the case of consumers, and a strong preference for healthcare workers in place of soap and water, to use 60% alcohol as a preferred method of hand sanitization. Their continuing preference for ethanol and the complete absence of any recommendation on available alternatives is not supported by the available literature (see attached). She also stated that CDC does not test individual commercial products which was what prompted the letter from John today (attached).

As you also may be aware GoJo, the makers of Purell, have been major contributors to CDC Foundations efforts to promote alcohol as a safe and preferred hand sanitizer (https://www.cdcfoundation.org/blog/clean-hands-count-story-success). While we cannot say with certainty this financial relationship had an impact on CDC's position and ranking of hand sanitization methods, it does cause one to question such a strong preference for alcohol and the lack of mention of other FDA compliant approaches ,given that the available literature does not appear to support such a preference in all cases.

The CDC's alcohol only recommendation for acceptable hand sanitizers is putting the US public at risk when alcohol-based sanitizers are not available due to physical shortages or lack of availability as a result of regulatory restrictions. This position puts the CDC at odds with other governmental agencies (FDA, FAA, etc) and will eventually come back to discredit the CDC when there is an outbreak of an alcohol resistant pathogen, such as E. faecium resulting in increased HAIs when there was an approved OTC hand sanitizing agent which they ignored. Relationships, such as the clean hands campaign emphasizing alcohol and supported by GoJo,

has the potential to cast a long dark shadow on the credibility of CDC. The messaging from CDC continues to put people who cannot use, or do not have access to, alcohol-base hand sanitizers at continuing risk due to their lack of mention of other alternatives.

We are committed to continuing to try and engage and work with CDC and other governmental agencies to update the current recommendations to reflect current science in the area of hand hygiene. This would ensure people are aware of available options which are consistent with their needs and beliefs. However, there will be a point where CDC's continuing lack of engagement will require we consider pursuing other avenues to try and address what we believe are significant concerns.

We appreciate everyone of you and your team's willingness to try and assist us in changing hand hygiene and improving healthcare. I always appreciate any thoughts or suggestions you believe would help get past the current logjam.

Thanks,

Kirk Kimmerling DDS Founder/CA
KHG FiteBac
FiteBac SkinCare, LLC

CDC Correspondence

Nikki Romanik
nromanik@cdc.gov
Nikki,

Kirk and I want to thank you for reaching out this past Monday in response to the letter noting our concerns with CDCs approach, and current recommendations, on hand hygiene protocols. Without rehashing the arguments outlined in our previous letter, we are concerned the current CDC recommendations of

(i) soap and water for 20 seconds

(ii) alcohol based sanitizers when soap and water are not available

(iii) ignores both the available science and the realities of modern life, as we outlined in our letter.

As you know, our concern is around CDC including only alcohol and not indicating other FDA compliant OTC sanitizers, namely those containing the broad spectrum antimicrobial BZK, in their recommendation for alternative when soap and water are not available. We are not at all requesting CDC recommend all are equal in all situations, nor are we averse to a prioritization based on the scientific literature, but their absence from the list, even when they are considered broad spectrum and their efficacy is known, is at the least, misleading.

I do have a question from our conversation on Monday, where you stated something along the lines of CDC does not test individual products. While I understand CDC's role is not to act as a testing or recommendation laboratory for industry, there is nothing inherently wrong with using commercially available products in testing as this is what is actually available to the consumer and healthcare worker. Also, performance may be impacted by how the product is formulated. For example, gel formulations can be designed to enhance persistence on the skin which may translate to durable activity over time. A blanket avoidance of testing commercially available products would thus appear to be short-sighted as sometimes it is the technology, and not the active ingredient alone, which contributes to the efficacy.

Again, I want to thank you for taking the time to talk with us concerning our letter and in opening a direct line

of communication between ourselves and your office.

Best regards,
John
John W Sharkey, Ph.D.
Chief Executive Officer

PubMed Study

Evaluation of a benzalkonium chloride hand sanitizer in reducing transient Staphylococcus aureus bacterial skin contamination in health care workers.

https://www.ncbi.nlm.nih.gov/pubmed/31668935

--
Kirk Kimmerling DDS Founder/CA
KHG FiteBac
FiteBac SkinCare, LLC
3698 Largent Way NW, Ste 101
Marietta, GA 30064
(b)(6) (c)
770-218-6221 (w)
http://khgfitebac.com

The more people know about something, the better, because the chances of someone knowing a solution to an issue are greater.

Stay Healthy > fiteBac.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/20/2020 2:28:28 PM
To: Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]
Subject: Fwd: CDC Summary for Clinicians on COVID Potential Therapies
Attachments: 20200319 Information for Clinicians on COVID-19 Therapies revised_FDA.docx

---

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 20, 2020 at 2:18:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: CDC Summary for Clinicians on COVID Potential Therapies

Dr. Hahn, please see attached CDC's document with one comment that FDA has. Just let me know if you have any questions.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 3:08:19 PM
To: Debi Birx MD (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HH (b)(5)
Subject: Fwd: CDC Summary for Clinicians on COVID Potential Therapies
Attachments: image002.png; ATT00001.htm; 20200319 Information for Clinicians on COVID-19 Therapies revised_FDA.docx; ATT00002.htm

(b)(5)

Sent from my iPad

Begin forwarded message:

From: "Guram, Jeet" <Jeet.Guram@fda.hhs.gov>
Date: March 20, 2020 at 2:18:47 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: CDC Summary for Clinicians on COVID Potential Therapies

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--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/20/2020 3:09:36 PM
To: tyler.a.mcguffee2@ovp.eop.gov
Subject: Fwd: CDC Summary for Clinicians on COVID Potential Therapies
Attachments: image002.png; ATT00001.htm; 20200319 Information for Clinicians on COVID-19 Therapies revised_FDA.docx; ATT00002.htm

Sent from my iPad

Begin forwarded message:

From: "Guram, Jeet" <Jeet.Guram@fda.hhs.gov>
Date: March 20, 2020 at 2:18:47 PM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Subject: CDC Summary for Clinicians on COVID Potential Therapies

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--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Jerry Cuttler [jerrycuttler@rogers.com]
Sent: 3/20/2020 3:09:59 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Chest X-ray as potential remedy for COVID-19 disease, resend
Attachments: Cuttler-2020Mar20_Letter to Hahn regarding COVID-19.pdf; Potential remedy for COVID-19 disease; 0.5 Gy chest X-ray

Dear Dr. Hahn

I sent you my recommendation for a COVID-19 remedy in email format yesterday and would like to update it in the attached formal letter.

(b)(4)

I look forward to your favorable response.

Sincerely

Dr. Jerry Cuttler, DSc

From: Daniel G. Tenen [csidgt@nus.edu.sg]
Sent: 3/20/2020 8:33:49 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: Li Chai [lchai@bwh.harvard.edu]; Miao Liu [mliu0@bwh.harvard.edu]
Subject: convalescent plasma transfusions
Attachments: FDA Hahn.pdf; NEJM Submission 2020 03-03.pdf

Dear Dr. Hahn,

After hearing you speak at the President's press conference yesterday, please see the attached letter regarding potential adverse effects of convalescent plasma transfusions and our manuscript (so far rejected) on it. We would appreciate any input.

Sincerely,

Dan Tenen

From: Kevin Parker [(b)(6)]
Sent: 3/21/2020 12:08:00 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Chloroquine

Stephen,

Please approve Chloroquine under an emergency situation for use against Covid-19 but caution people letting them know it is still in trial. This way manufacturers will start mass production and doctors will continue to prescribe it. Other wise you are costing Americans their lives. I'm not sure how you can live with that.

Kevin

On Fri, Mar 20, 2020, 4:05 PM Kevin Parker <(b)(6)> wrote:

> Hi Stephen,
>
> Nice job of dropping our medical system below South Korea, China, Australia, and more. Last I heard our Health Care was ranked 31st world wide. Your lack of vision and inability to work with other countries who are now using Chloroquine as a treatment for the Coronavirus is disturbing. I'll make sure to write whoever appoints you so that you do not get reappointed. I'm sure you'll make this medicine available to your family if they get sick.
>
> Please listen to what is working in other countries and don't wait months for a double blind study.
>
> Kevin Parker

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 5:28:25 PM
To: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: Re: TWEETS for REVIEW: Cepheid // State-Auth Test // Fraudulent Kits // Gloves // Primerdesign

Nice. I think (b)(5)
(b)(5)
S

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Date: March 21, 2020 at 5:20:56 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: TWEETS for REVIEW: Cepheid // State-Auth Test // Fraudulent Kits // Gloves // Primerdesign

Good afternoon. Several topics for your review. Thanks! --Brad

===

Cepheid EUA
Thread:

1. Today, @US_FDA issued the first emergency use authorization (EUA) for a point-of-care #COVID19 diagnostic for the Cepheid Xpert Xpress SARS-CoV-2 test. http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-use-authorization-point-care-diagnostic **[EUA GRAPHIC]**

2. Point-of-care testing means results are delivered in patient care settings like hospitals & urgent care instead of sending samples to a lab. With today's authorization, there is now an option for testing at the point of care, giving patients access to more immediate results.

(b)(5)

State-Authorized Tests

Thread:

1. Last week, we updated our diagnostic testing policy for #COVID19 to advance U.S. testing capacity – where w/ certain state labs, states can take responsibility under their law and processes for COVID-19 patient tests, similar to the action FDA took for NY. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-more-regulatory-relief-during-outbreak-continues-help

2. I'm pleased to announce that under this new policy, Washington state & Nevada have joined New York in setting up similar systems for authorizing #COVID19 diagnostic tests. Labs authorized by these states won't be expected to pursue an EUA with FDA.

Fraudulent Test Kits

(b)(5)

1. FDA is actively and aggressively monitoring for any firms marketing products with fraudulent #COVID19 diagnostic, prevention and treatment claims as part of our ongoing efforts to protect public health during this pandemic. http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits

(b)(5)

Glove Conservation Tweets

Thread

1. Recognizing that the need for personal protective equipment (PPE), such as surgical & examination gloves, may outpace the supply available during the #COVID19 pandemic, FDA has published a letter to health care providers sharing conservation strategies. https://www.fda.gov/medical-devices/letters-health-care-providers/medical-glove-conservation-strategies-letter-health-care-providers

2. Proposed conservation strategies include using nonsterile disposable patient examination gloves for routine patient care or using medical gloves beyond the manufacturer-designated shelf life in a setting where there is a lower risk of transmission.

3. FDA is collaborating with manufacturers of medical gloves to better understand the current supply chain issues related to the #COVID19 pandemic and to help mitigate any widespread shortages of these products. Find more info from our #FAQs https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-medical-gloves

(b)(5)

PrimerDesign EUA
Thread:

1. Yesterday, FDA issued a diagnostic EUA to Primerdesign Ltd. for its Primerdesign Ltd COVID-19 genesig Real-Time PCR assay https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd
2. Developers can find answers to questions about the EUA process and other #COVID19 diagnostic test-related questions on our #FAQ page: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/21/2020 6:10:33 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Thorpe, Valarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4263524681134dc4a9c7f8ff9752864b-Valarie.Tho]
Subject: RE: TWEETS for REVIEW: Cepheid // State-Auth Test // Fraudulent Kits // Gloves // Primerdesign

Apologies for the delay – just seeing this now but it looks like Steve cleared – thank you

---

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:23 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: TWEETS for REVIEW: Cepheid // State-Auth Test // Fraudulent Kits // Gloves // Primerdesign

(b)(5) TY.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, March 21, 2020 5:21 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
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(b)(5)

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(b)(5)

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(b)(5)

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(b)(5)

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2. Developers can find answers to questions about the EUA process and other #COVID19 diagnostic test-related questions on our #FAQ page: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

Brad Kimberly
Director, Social Media

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Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1082 | Cell (b)(6)
brad.kimberly@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/22/2020 8:09:59 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Information for WHTF March 22.docx
Attachments: Information for WHTF March 22.docx; ATT00001.txt

Morning - here are talkers for today. The first 2 components, ventilator guidance and chloroquine supply, are what you asked for. Let me know if you need anything else.

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 3/22/2020 5:51:22 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: COVID-19 Serologic Tests

Thanks, Jeff. Peter, I want us to remove any barriers to the development of convalescent plasma and hyperimmune globulin. Please let me know how we can engage industry or others to expedite.
Thanks

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: March 22, 2020 at 5:42:18 PM EDT
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: COVID-19 Serologic Tests

From: LORCAN KILROY [(b)(6)]
Sent: 3/22/2020 8:47:03 PM
To: (b)(6) FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Peter.Piot@lshtm.ac.uk
CC: (b)(6)
Subject: URGENT, Re: COVID -19 strengthening and multiplying itself in culture while sitting on top of mucus membranes during incubation, isolated from t-cells, and need for otc alcohol based mouthwash/deep gargling and nasal swabbing protocol
Attachments: Piot re. covid-19.pdf

Peter Piot

Director, London School of Hygiene and Tropical Medicine

Keppel St, Bloomsbury, London WC1E 7HT, United Kingdom

(b)(6)

Dear Dr. Piot,
Please find attached in re. the above subject. I have copied US health officials.
Thank you,
Lorcan T. Kilroy M.F.A.
Los Angeles

From: Robert Rutkowski (b)(6)
Sent: 3/23/2020 7:22:57 AM
To: engagement@ostp.eop.gov; Elizabeth_Strimer@mcconnell.senate.gov; dan.meyer@mail.house.gov; cdcwashington@cdc.gov; robertredfield@cdc.gov; Secretary@HHS.gov; Azar, Alex (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4db7abd56a7e478883f5cd8e2e8a18d3-HHS-Alex.Az]; george.kundanis@mail.house.gov; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; rocint@schumer.senate.gov
Subject: Why did the USA fail in its initial coronavirus response?

Mr. Donald J. Trump
c/o Director of Presidential Correspondence
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500
FAX: 202-456-2461
Phone: (202) 456-7000
engagement@ostp.eop.gov

Senator Mitch McConnell
RUSSELL SENATE OFFICE BUILDING
WASHINGTON DC 20510
Phone: (202) 224-2541
Elizabeth_Strimer@mcconnell.senate.gov

Representative Kevin McCarthy
Republican Majority Leader
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Washington, DC 20515
Phone: (202) 225-2915
Fax: (202) 225-2908
dan.meyer@mail.house.gov

Speaker Nancy Pelosi
OFFICE OF THE SPEAKER
H-232 The Capitol
Washington, DC 20515
Phone: (202) 225-0600
Fax: (202) 225-2012
george.kundanis@mail.house.gov

Senator Chuck Schumer
Democratic Leader
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Washington, DC 20510
rocint@schumer.senate.gov

Representative Steny Hoyer
House Majority Leader
Legislative Correspondence Team
1705 Longworth House Office Building
Washington DC 20515
Office: (202) 225-4131
Fax: (202) 225-4300
https://www.majorityleader.gov/content/email-whip

Robert R. Redfield, Director
CDC
1600 Clifton Road
Atlanta, GA 30329-4027
Email: cdcwashington@cdc.gov, robertredfield@cdc.gov
Phone: (202) 245-0600
Fax: (202) 245-0602 or (202) 245-0599

Alex Azar, Secretary of Health and Human Services

Office of the Secretary
U.S. Department of Health & Human Services
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Phone: 202-690-7000
Secretary@HHS.gov, Alex.Azar@hhs.gov

Stephen M.Hahn, M.D.
Commissioner
via Caitlin Pennington, Executive Assistant
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
caitlin.pennington@fda.hhs.gov, stephen.hahn@fda.hhs.gov

Re: Why did the USA fail in its initial coronavirus response?

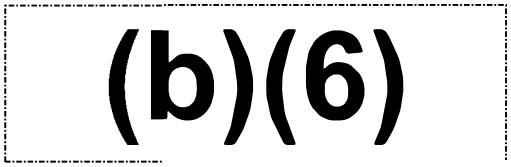
Dear Congressional Leaders, Commissioner, Director, Secretary and Mr. Trump:

It's a failing, let's admit it' says top health official, Dr Anthony Fauci. It took a month for a working coronavirus test to be rolled out around the country, while other countries were testing thousands of people. How was this allowed to happen? The Inquiry, explores the ways in which the US lost valuable time in dealing with the coronavirus and how the US health system could make things more difficult still.

Listen to:
Why did the USA fail in its initial coronavirus response?
https://www.bbc.co.uk/sounds/play/w3csythj

Take time to review this podcast and give it the weight it deserves.

Yours sincerely,
Robert E. Rutkowski



From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/24/2020 6:29:25 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Vizient Recommendations re: chloroquine & hydroxychloroquine

Ok then I won't

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 24, 2020 at 5:56:14 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Vizient Recommendations re: chloroquine & hydroxychloroquine

Sure. Don't think he needs to do anything though. Other folks will engage where we can.

Sent from my iPhone

On Mar 24, 2020, at 5:40 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Ok to ask Anand to work with them? I don't have bandwidth.
S

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 24, 2020 at 5:15:18 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Vizient Recommendations re: chloroquine & hydroxychloroquine

I sent to ASPR and FEMA and let drug shortage team know in CDER. Just sharing with you for awareness.

Sent from my iPhone

On Mar 24, 2020, at 5:06 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Keagan,
How should we proceed? OK to ask Anand to work with CDER and ASPR on this?
Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 23, 2020 at 5:22:37 PM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: FW: Vizient Recommendations re: chloroquine & hydroxychloroquine

Scary stats.

From: Krilow,Shoshana <shoshana.krilow@vizientinc.com>
Sent: Monday, March 23, 2020 2:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Kistner,Daniel <Daniel.Kistner@vizientinc.com>
Subject: Vizient Recommendations re: chloroquine & hydroxychloroquine

Hi Keagan,

I know you are aware of the recent spike in demand for chloroquine (6482%) and hydroxychloroquine (2196%) since they have been identified as potential treatments to COVID-19. For example, prior to COVID-19 we would see on average about (b)(4) tablets of hydroxychloroquine purchased a day by our members while last week we saw an average of about (b)(4) a day ordered with only about 12% of orders being fulfilled. While many manufacturers are coming to market to make chloroquine and hydroxychloroquine it will take weeks and, until then, the market will survive on the products that are in the channel. Unfortunately, we are hearing more and more of prophylaxis and unnecessary refill scripts being written and filled which is keeping that product potentially off the shelves of hospitals to treat COVID-19 confirmed cases.

As a follow-up to our President and CEO, Byron Jobe, meeting with the Vice President and Administrator Verma, we wanted to pass along additional recommendations (attached) regarding how to mitigate any shortage related to these drugs by making sure the product is being used for FDA-approved indications and in the hospital setting as much as possible to treat patients who are positive for COVID-19. We are also sharing these with the Vice President's office.

Happy to answer any questions you may have. Thank you, and the Commissioner, for all of your work. We know these are trying times and we hope we can be helpful to you.

Shoshana

Shoshana Krilow
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799 9th St NW Ste 210
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From: McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]
Sent: 3/25/2020 12:57:46 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: RE: Info for Pocan call

1. Shortages—overall, please confirm how many drugs are currently in shortage and if any are related to COVID.

- Currently, the agency has 146 drug listed on our drug shortages website, some are considered resolved and other are listed as currently in shortage. There are 99 considered to be currently in shortage.
- Because the situation is very dynamic, noting the exact number of shortages directly associated with the COVID-19 outbreak would be misleading. Firms do not have to indicate to FDA if a shortage is due to the outbreak or not.
- *(Note: further contextual talking points included in answer to second question)*

2. What are we seeing as far as spot shortages related to COVID? Please provide any general info. And what are we monitoring right now as potential problems? What alternatives are we recommending for any concerns?

- The Agency continues to hear from various sources about a number of spot shortages that are regional or possibly due to surges in demand due to COVID-19 treatment, transportation of raw materials, and other factors related to the COVID-19 outbreak.
- We are acutely aware of the hardships individual pharmacies, hospitals, health systems and other health care practitioners are experiencing. As a doctor, I know how hard these professionals are working in a stressful time and want you to know we are doing everything in our power to help the people that are working day and night in the trenches to help with this public health emergency.
- FDA actively monitors the status of medications that are in shortage or appear likely go into shortage, including drugs that are currently being used to treat individuals with COVID-19.
- The Agency is in constant communication with manufactures to help facilitate the companies in making adjustments and support getting more product back into the supply chain.
- FDA has also been touch with manufacturers of human drugs, not only to remind them of applicable legal requirements for notifying the FDA of anticipated supply disruptions, but also asking them to evaluate their entire supply chain, including active pharmaceutical ingredients.
- Lastly, we are in touch with other entities in the supply chain to help address any other bottlenecks in the supply chain that may be leading to shortages.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 12:49 PM
To: McBride, Maren <Maren.McBride@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Re: Info for Pocan call

Thanks

From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Date: March 25, 2020 at 12:48:19 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Info for Pocan call
Importance: High

Hi—below is some of the info you asked for RE: to Pocan call. I'm still waiting for the drug shortage stuff. Should have in a few mins.

Diagnostic Testing Data

- Testing for COVID-19 is occurring throughout the United States in our State and Local Public Health Labs, commercial laboratories, and academic/hospital laboratories.
  - Yesterday (March 24), the Public Health Laboratories reported out results for 6,463 sample/patients. The total number of tests the PHLs have performed to date is 89,863.
  - Commercial laboratories (ACLA laboratories) ran 57,000 tests yesterday for a cumulative total of 338,000.
  - The CDC has tested 4,754 samples.
  - Together, the State/Local Public Health Laboratories and the Commercial Laboratories have tested 432,617 samples.
  - Note that these numbers do not include numbers from the Academic/Hospital testing laboratories, however the HHS-FEMA diagnostic task force is in the process of accessing and integrating this information into regular reporting.

Current situation in Wisconsin

As of March 24, there are 416 positive COVID-19 cases in Wisconsin. According to the Wisconsin Department of Health Services, as of March 24, there have been 5 deaths associated with COVID-19 in Wisconsin and 7,050 negative tests in Wisconsin. Public and private schools in Wisconsin are closed through April 6, 2020 and under an executive order issued by Governor Tony Evers on March 23, 2020, non-essential businesses are to be closed from March 25, 2020 through April 24, 2020.

To date there has been one delivery from the Strategic National Stockpile to Wisconsin. On March 20th, the following supplies were delivered (*Note: These numbers may vary slightly based on packaging*). There is a second shipment in process.

N95 Masks – 54,709
Surgical Masks – 130,326
Face Shields – 24,816
Surgical Gowns – 20,233
Coveralls – 104
Gloves – 72,044

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/25/2020 1:59:24 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: 2 PM TALKERS: Commissioner Talkers for AdvaMed 3.25.2002

Importance: High

Talkers for 2 PM call, below.

Frank

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 1:14 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Commissioner Talkers for AdvaMed 3.25.2002

Hi Jeff -
Thank you. Colin and Frank will get these to Steve
Anand

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 1:11 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Fwd: Commissioner Talkers for AdvaMed 3.25.2002

For Steve for AdvaMed remarks.

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Date: March 25, 2020 at 1:01:18 PM EDT
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Commissioner Talkers for AdvaMed 3.25.2002

Jeff,

I hope these are helpful. I highlighted one item we did not discuss but thought it could be helpful to mention (unless you think its better to hold off). I also included more info re testing that I thought would be helpful to the commercial manufacturing side.

Please let me know if you have any questions; I know we don't have much time but am happy to work on this further if there is anything lacking.

Best,

Jennifer

(b)(5)

Jennifer Brown Tomasello, MPA
Senior Policy Adviser

Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
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https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E

From: Robert Rutkowski (b)(6)
Sent: 3/25/2020 5:14:43 PM
To: Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; public_affairs@gilead.com
Subject: After Caving on 'Orphan Drug' Designation, Gilead Must Commit to Licensing and Mass Production

Stephen M.Hahn, M.D.
Commissioner
via Caitlin Pennington, Executive Assistant
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
caitlin.pennington@fda.hhs.gov, stephen.hahn@fda.hhs.gov

Daniel O' Day
Chairman and Chief Executive Officer
Gilead Sciences
333 Lakeside Drive
Foster City, CA 94404
Phone: +1 650 574 3000
Fax: (650) 578-9264
E-mail: public_affairs@gilead.com

Re: After Caving on 'Orphan Drug' Designation, Gilead Must Commit to Licensing and Mass Production

Dear Commissioner and Chairman:

Shortly after groups demanded that Gilead Sciences relinquish its government-sanctioned monopoly guarantee for a potential COVID-19 treatment, the pharmaceutical giant agreed to do so.

It was outrageous that Gilead ever sought an "orphan drug" designation for remdesivir, which aims to treat a patient population that easily may number in the tens of millions in the U.S. alone. That designation would confer a special seven-year monopoly on the drug. Thankfully, under pressure, the company has backed down. There's no doubt that the prospect of an enormous public backlash is what made the difference.

But today's action is not enough. If remdesivir proves to be a viable treatment for COVID-19, then the world cannot afford to have one manufacturer maintain a monopoly over it, particularly given the huge amount of public investment that has gone into the drug. Gilead must do more than make vague promises of reasonable pricing. It should commit right now to license the right and needed know-how to manufacture remdesivir to all qualified producers, in exchange for a modest royalty.

If the drug proves viable as a COVID-19 treatment, the U.S. and the world will need the product available at a low price that reflects both the public health need and the potentially enormous market - with production at an unprecedented scale.

Yours sincerely,
Robert E. Rutkowski

CC:
Representative Steny Hoyer
House Majority Leader
Legislative Correspondence Team
1705 Longworth House Office Building
Washington DC 20515
Office: (202) 225-4131
Fax: (202) 225-4300
https://www.majorityleader.gov/content/email-whip

(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/25/2020 5:53:39 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Follow-up on Fraud/Fish Drug

We are presenting to the task force on Friday (CTAP) and also probably talking about the nationwide expanded access protocol for convalescent plasma. There is a British Medical Journal article from China published today that suggests there is substantial benefit.
S

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: March 25, 2020 at 5:44:08 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

Is that happening Friday? We just heard from CBER the blood donor guidance is going Friday, which is a big deal and we were hoping to do a media call on Friday.

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
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Cell **(b)(6)**
stephanie.caccomo@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:41 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

(b)(5) My two cents.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:39 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: Follow-up on Fraud/Fish Drug

This is so great, Michael. Thank you. I have a call with 5000 doctors on Saturday. Let's think about high level messages that I can give them during my opening remarks. The call is being arranged by Administrator Verma at CMS and I think it's a terrific opportunity to connect with the front line.
Similarly, I'll be on a call with the hospitals (again through CMS) on Monday. It's another opportunity to get our message out.
Steve

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: March 25, 2020 at 1:53:22 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Follow-up on Fraud/Fish Drug

Hi Dr. Hahn,

I wanted to follow up with you for your awareness about the work our entire communications shop has done/is doing to promote the Consumer Update we issued yesterday, entitled Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments, which includes warnings on fake tests and fish tank drug. I'm including the entire document below if you'd like to take a look.

(b)(5)

We are hopeful this will continue to help amplify our message in this area.

Thanks,

Michael

Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments

While many Americans are sheltering at home to help "flatten the curve" and slow the spread of coronavirus disease (also called COVID-19), they might be tempted to buy or use questionable products that claim to help diagnose, treat, cure, and even prevent COVID-19.
Because COVID-19 has never been seen in humans before, there are currently no vaccines to prevent or drugs to treat COVID-19 approved by the U.S. Food and Drug Administration (FDA). The FDA is working with vaccine and drug

manufacturers to develop new vaccines for and find drugs to treat COVID-19 as quickly as possible. Meanwhile, some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus.

These fraudulent products that claim to cure, treat, or prevent COVID-19 haven't been evaluated by the FDA for safety and effectiveness and might be dangerous to you and your family.

The FDA is particularly concerned that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications.

The FDA has also seen unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the only way to be tested for COVID-19 is to talk to your health care provider. The FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. You will risk unknowingly spreading COVID-19 or not getting treated appropriately if you use an unauthorized test. The FDA knows that having a home test for COVID-19 would be very helpful and is actively working with test developers on this. But currently the FDA has not authorized any home test for COVID-19.

There Are No Vaccines or Medicines for COVID-19, Yet

The FDA **is working with medical product developers** to rapidly advance the development and availability of vaccines and treatments for COVID-19. Although there are investigational COVID-19 vaccines and treatments being studied in clinical trials, these products are in the early stages of development. They haven't yet been fully tested for safety or effectiveness, or received FDA approval.

Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver.

The FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 diagnostic, prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unauthorized products with false or misleading claims. The FDA may send warning letters, or pursue seizures or injunctions against people, products, or companies that violate the law. We are also increasing our enforcement at ports of entry to ensure that fraudulent products do not enter the country through our borders.

In addition, the FDA is monitoring complaints of fake coronavirus treatments and tests. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations.

How to Protect Yourself and Your Family From Coronavirus Fraud

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat or cure COVID-19. There are no FDA-approved products to prevent COVID-19. Products marketed for veterinary use, or "for research use only," or otherwise not for human consumption, have not been evaluated for safety and should never be used by humans. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. Don't take any form of chloroquine unless it has been prescribed for you by your health care provider and obtained from legitimate sources.

Here are some tips to identify false or misleading claims.

- Be suspicious of products that claim to treat a wide range of diseases.
- Personal testimonials are no substitute for scientific evidence.
- Few diseases or conditions can be treated quickly, so be suspicious of any therapy claimed as a "quick fix."
- If it seems too good to be true, it probably is.
- "Miracle cures," which claim scientific breakthroughs or contain secret ingredients, are likely a hoax.
- Know that you can't test yourself for coronavirus disease.

If you have symptoms of COVID-19, follow the Centers for Disease Control and Prevention's guidelines, and speak to your medical provider. Your health care provider will advise you about whether you should get tested and the process for being tested in your area.
If you have a question about a treatment or test found online, talk to your health care provider or doctor. If you have a question about a medication, call your pharmacist or the FDA.
The FDA's Division of Drug Information (DDI) will answer almost any drug question. DDI pharmacists are available by email, druginfo@fda.hhs.gov, and by phone, 1-855-543-DRUG (3784) and 301-796-3400.
The sale of fraudulent COVID-19 products is a threat to the public health. If you are concerned about the spread of COVID-19, talk to your health care provider and follow the advice of FDA's federal partners about how to prevent the spread of this illness.

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
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michael.felberbaum@fda.hhs.gov

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/25/2020 5:56:17 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Follow-up on Fraud/Fish Drug

We are planning a potential media call on blood donation guidance on Friday.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:55 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

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Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

Excellent point

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Date: March 25, 2020 at 5:45:31 PM EDT
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
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Press Officer

Office of Media Affairs
Office of External Affairs
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Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

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Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
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To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
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Michael

Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments

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The FDA **is working with medical product developers** to rapidly advance the development and availability of vaccines and treatments for COVID-19. Although there are investigational COVID-19 vaccines and treatments being studied in clinical trials, these products are in the early stages of development. They haven't yet been fully tested for safety or effectiveness, or received FDA approval.

Fraudulent COVID-19 products can come in many varieties, including dietary supplements and other foods, as well as products claiming to be tests, drugs, medical devices, or vaccines.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online. The agency will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

Recently, the FDA and the Federal Trade Commission issued warning letters to seven companies for selling fraudulent COVID-19 products. The products cited include teas, essential oils, tinctures, and colloidal silver.

The FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 diagnostic, prevention and treatment claims. The FDA is exercising its authority to protect consumers from firms selling unauthorized products with false or misleading claims. The FDA may send warning letters, or pursue seizures or injunctions against people, products, or companies that violate the law. We are also increasing our enforcement at ports of entry to ensure that fraudulent products do not enter the country through our borders.

In addition, the FDA is monitoring complaints of fake coronavirus treatments and tests. Consumers and health care professionals can help by reporting suspected fraud to the FDA's Health Fraud Program or the Office of Criminal Investigations.

How to Protect Yourself and Your Family From Coronavirus Fraud

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat or cure COVID-19. There are no FDA-approved products to prevent COVID-19. Products marketed for veterinary use, or "for research use only," or otherwise not for human consumption, have not been evaluated for safety and should never be used by humans. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. Don't take any form of chloroquine unless it has been prescribed for you by your health care provider and obtained from legitimate sources.

Here are some tips to identify false or misleading claims.

- Be suspicious of products that claim to treat a wide range of diseases.
- Personal testimonials are no substitute for scientific evidence.
- Few diseases or conditions can be treated quickly, so be suspicious of any therapy claimed as a "quick fix."
- If it seems too good to be true, it probably is.
- "Miracle cures," which claim scientific breakthroughs or contain secret ingredients, are likely a hoax.
- Know that you can't test yourself for coronavirus disease.

If you have symptoms of COVID-19, follow the Centers for Disease Control and Prevention's guidelines, and speak to your medical provider. Your health care provider will advise you about whether you should get tested and the process for being tested in your area.

If you have a question about a treatment or test found online, talk to your health care provider or doctor. If you have a question about a medication, call your pharmacist or the FDA.

The FDA's Division of Drug Information (DDI) will answer almost any drug question. DDI pharmacists are available by email, druginfo@fda.hhs.gov, and by phone, 1-855-543-DRUG (3784) and 301-796-3400.

The sale of fraudulent COVID-19 products is a threat to the public health. If you are concerned about the spread of COVID-19, talk to your health care provider and follow the advice of FDA's federal partners about how to prevent the spread of this illness.

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell (b)(6)
michael.felberbaum@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/25/2020 6:15:24 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Follow-up on Fraud/Fish Drug

(b)(5) am ok with your suggestion to do the blood media call in the am
S

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 25, 2020 at 6:13:13 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

(b)(5)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:11 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Follow-up on Fraud/Fish Drug

Would want your advice on that

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: March 25, 2020 at 5:54:53 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
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Subject: RE: Follow-up on Fraud/Fish Drug

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Date: March 25, 2020 at 5:45:31 PM EDT
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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Subject: RE: Follow-up on Fraud/Fish Drug

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:44 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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If you are announcing CTAP Friday, you should talk a lot about that. I think fraud would be helpful too. My two cents.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 5:39 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
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Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
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Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell **(b)(6)**
michael.felberbaum@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/25/2020 6:24:57 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Expand COVID-19 Testing

Colin
Can you handle?
Thanks
S

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 25, 2020 at 6:23:46 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: RE: Expand COVID-19 Testing

You can filter all these letters like this to Colin or Lindsay Tobias to get to exec sec to manage.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:17 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Expand COVID-19 Testing

Who should this go to?

From: Sim Meak <sim.meak@maine.gov>
Date: March 20, 2020 at 8:30:41 AM EDT
To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>
Subject: Expand COVID-19 Testing

Sim Meak
221 State St
Augusta, ME 04330

March 20, 2020

Dear Stephen M. Hahn,

Dear President Trump:

I am writing as a member of our nation's laboratory medicine team, which includes pathologists and laboratory professionals, to raise my concerns about America's capacity to meet patient testing needs for COVID-19. To date, other countries are doing a better job addressing the diagnostic needs of their patients.

Our government needs to take assertive action to expand the capacity of our nation's clinical laboratories to provide diagnostic testing for the COVID-19 virus in order to hasten its containment. The United States' clinical laboratories are having difficulties securing the resources needed for COVID-19 testing. Labs need an unfettered supply of test kits, instrumentation, reagents and DNA extraction kits, as well as the virus samples necessary to accurately and reliably identify this virus. In addition, clinical labs and their vendors need enhanced regulatory flexibility to meet these needs. Commercial vendors, who have test materials to detect COVID-19, are restricted from providing guidance on the use of these products, i.e., test methods, because the tests are not FDA cleared. This restriction, which is acceptable at most times, delays the implementation of critically needed assays in times of crisis. We request that vendors are temporarily released from these restrictions and are allowed to provide guidance for testing for the COVID-19, which will facilitate the implementation and more wide-spread use of these tests.

I urge you to direct the federal government to take immediate action to help our nation's laboratories expand laboratory testing capacity needs as quickly as possible.

As a laboratory professional dedicated to providing quality patient care, I stand ready to assist you in our nation's time of need.

Sincerely,

Sincerely,
Sim Meak

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/25/2020 6:25:12 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Expand COVID-19 Testing

Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 25, 2020 at 6:23:28 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: Expand COVID-19 Testing

I will send to exec sec

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:17 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Expand COVID-19 Testing

Who should this go to?

From: Sim Meak <sim.meak@maine.gov>
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Sent: 3/25/2020 7:35:29 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: For Review: Op-Ed from VP office

Thx

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: March 25, 2020 at 7:23:19 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: For Review: Op-Ed from VP office

Thank you. I made edits a few days ago and passed them to Stephanie

On Mar 25, 2020, at 6:14 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: March 22, 2020 at 8:49:55 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: For Review: Op-Ed from VP office

Dr. Hahn-
For your review, an op-ed on our COVID efforts, written by VP's office and edited by FDA. Attached and copied below. Let us know if any concerns. VP's office will handle placing it. Thank you!

Commissioner Hahn
Op Ed
3.22.20

With the spread of the coronavirus disease throughout the United States, America's health care system faces its greatest challenge in decades. In response to this national and global emergency, President Donald Trump is bringing the full authority and resources of the federal government to slow the spread of the virus and to protect the American people.

I am proud to lead the Food and Drug Administration, which plays an indispensable role in the American health care system and in our country's response to coronavirus. We work every day to ensure the safety and effectiveness of the drugs, biological products, and medical devices that the American people use to stay healthy. Our oversight of medical products facilitates America's dynamic

and innovative medical research and development, which has changed our country and our world for the better.

With these unique capabilities, under the leadership of President Trump we've taken action to fight the coronavirus since the outbreak first began.

The FDA does not develop tests, that's up to the private sector and other federal government partners, like the CDC, but our actions since January have helped to dramatically expand the availability of testing.

We continue to work around the clock to review testing authorization requests, including authorizing multiple tests within 24 hours of receiving the application.

In addition, this past weekend, we also authorized the first point-of-care diagnostic for coronavirus. Results are delivered directly in patient care settings – such as hospitals and urgent care – instead of sending samples to a lab. This approach will give patients more immediate access to results and health care providers more ability to provide proper care upon diagnosis.

We've been very flexible and adaptive during this pandemic. For instance, nearly a month ago, we relaxed the regulatory requirements on laboratories so they could more nimbly to develop coronavirus tests without FDA serving as a gatekeeper. When we saw it working, we leveraged the skills and expertise of our state partners, to allow states to authorize tests that their public health laboratories have developed and to commercial test manufacturers to begin distributing tests for patient testing without waiting for FDA authorization.

We are staffing a 24-hour hotline 7-day-a-week, 888-INFO-FDA, for help with questions they may have about supplies or test development.

All of these actions have greatly increased the number of tests available across America. But I cannot stress enough that while we are providing regulatory flexibility, we are still working to ensure that the tests are accurate. We've heard about inaccurate tests in other parts of the world, which is especially dangerous in a pandemic like this. We cannot have tests that do not provide reliable results. Accurate tests will make the difference in how quickly we can respond to this pandemic.

And we're not only taking steps to expand accurate testing. We're also working to streamline our processes for coronavirus vaccines and therapeutics. In nearly record time, the National Institutes of Health announced that a potential vaccine has already begun a phase 1 clinical trial. If strong data demonstrates the safety and efficacy of a vaccine, I am committed to streamlining the review a vaccine as quickly as we are able.

We've already seen progress towards the development of drugs to treat coronavirus, and we look forward to continuing to work with the public, academic and private sectors to make those drugs available to patients as quickly as possible. There are many tools we can use to facilitate the development of medicines and get treatments to patients quickly such as through clinical trials of new drugs or facilitating the availability of drugs like chloroquine that are already approved for other uses. While clinical trials are ongoing to assess the benefits of these drugs, doctors may prescribe such drugs in the course of their medical practice for other diseases, like COVID-19, when they judge that it could help their patients.

We're also actively monitoring the medical supply chain and doing what we can to mitigate any shortages. For instance, to prevent a shortage of hand sanitizer, we issued a policy for new sources of alcohol-based hand sanitizer to come to the market. We have also been aggressively working with partners to identify and mitigate shortages of personal protective equipment by granting authorizations for alternative sources for masks, gowns, and gloves. And we are relaxing red tape to allow non-traditional manufacturing of personal protective equipment.

This past weekend, we also took action to expand the availability of ventilators—crucial for patient treatment during the COVID-19 pandemic—by allowing other manufacturers, like auto manufacturers, to make components needed for ventilators.

We also keep looking across all the products we regulate, including food, for ways we can reduce regulatory burdens. While our grocery stores are facing unprecedented demand, we are working with industry to minimize disruptions in the supply-chain due to coronavirus travel restrictions. Last week, we released a policy to help minimize disruptions so that the food industry can meet the demand while also continuing activities that are designed to ensure food safety.

These are all important actions, but the American people can be assured that this is just the beginning. We will take many other meaningful measures in the weeks ahead. Under President Trump, the FDA will continue to take strong action to protect the American people.

Stephanie Caccomo
Press Officer

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

<200320 corona oped FDA_fda edits_3.22.20_830pm.docx>

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/27/2020 6:58:55 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: WH Presser TPs 03262020 1040pm.docx
Attachments: WH Presser TPs 03262020 1040pm.docx; ATT00001.txt

Talkers for the presser. We tried to dumb it down, see if this works.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 9:28:15 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: CDRH response update

Please print for me
thanks

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Date: March 26, 2020 at 6:52:03 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: CDRH response update

Dr Hahn,

Below please find a list of CDRH's emergency response actions from yesterday as well as anticipated actions in the coming 48 hours.

March 25, 2020 actions

- Ventilators:
  - CDRH issued a blanket **EUA** for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA.
  - CDRH authorized an **EUA** for Beijing Aeonmed Co., Ltd., Beijing, China, for an unapproved ventilator model VG70 that NY state has purchased. The ventilators will be imported next week.
  - A CDRH subject matter expert worked with the FEMA ventilator surprise chain task force to facilitate the availability of a splitter to enable a single ventilator to support multiple patients at one time.
  - CDRH authorized an **EUA** for the Prisma Health 3D printed Ventilator Expansion Splitter (VESper) that allows one ventilator to be used on more than one patient.
  - CDRH met with multiple stakeholders developing creative solutions to a potential ventilator shortage.

(b)(5)

- PPE
  - CDRH published **Guidance** on "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency."
- Diagnostics:
  - CDRH held a Town Hall/Webinar with 1,000 participants during which we provided an overview of the March 16th guidance on diagnostics and answered questions from labs.
  - CDRH authorized **EUAs** for SARS-CoV-2 diagnostics from Avellino Labs and Perkin Elmer. Avellino labs notified FDA and was offering their test under the policy outlined in the Feb. 29th guidance.

- We now have 18 authorized diagnostics and over 100 notifications from developers offering tests under the Feb 29th/March 16th guidance.

Anticipated actions in the next 48 hours

(b)(5)

- CDRH intends to publish Guidance on gowns. The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance
- CDRH intends to publish Guidance on "Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency." The guidance will address appropriate labeling for these products during the COVID-19 public health emergency without requiring 510(k) submission and clearance.

Elizabeth
Elizabeth Hillebrenner
Associate Director for Scientific and Regulatory Programs
Center for Devices and Radiological Health
Office of the Center Director
U.S. Food and Drug Administration
Tel: 301-796-6346
elizabeth.hillebrenner@fda.hhs.gov

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

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 10:46:47 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Sterigenics Sterilization Capacity urgently needed

Ok thanks. This came up on our call with Governor Kemp.
Steve

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 27, 2020 at 10:01:39 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Sterigenics Sterilization Capacity urgently needed

They aren't allowing full capacity I guess. FEMA thinking about taking matters in their own hands. See below, this is the first time this authority will be used. Which could have some optics issues for us since we sent GA letter this week (b)(5)
(b)(5)

- FEMA is seeking to issue an order pursuant to the DPA to fully reopen the Sterigenics EtO sterilization facility in Smyrna, Georgia, and bring it to full capacity. **(b)(5)** .
- FEMA apparently believes this is necessary in light of the current status of the facility and restrictions imposed related to ongoing issues between the company and local government (Cobb County).

Sent from my iPhone

On Mar 27, 2020, at 9:26 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

I thought this was resolved. Could you check with Brian Harrison?
Thanks
S

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

Thank you for your continued efforts on behalf of patients as we continue to combat COVID-19.

I will be brief, the response from Cobb County has been very disappointing. They are only allowing for a limited reopening of the Sterigenics facility and for the sterilization of PPE only. We need sterilization capacity for critical Medical Devices and we need it immediately.

I respectfully ask you and your team to revisit the discussion with Cobb County. I attach the response from Sterigenics for your reference.

Thanks again for your help,

Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: (b)(6)
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: Liam Kelly <liam.kelly@teleflex.com>
Date: Wednesday, March 18, 2020 at 8:37 AM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Dr Hahn,
Thank you for your attention to the sterilization issue. This will assist companies like Teleflex who are seeing increased demand for products needed to treat COVID-19 patients. Without this capacity we may have a supply issue which could impact patient care. It is in times of crisis that almost always brings out the best in people, companies and agencies. We should learn and make it every day life!
On a separate but related topic, I would like to make you aware of an effort that Teleflex is working on pertaining to a Point of Care, fully portable solution for the rapid identification of the presence of the novel coronavirus in respiratory secretions. We are in contact with BARDA and are submitting an application later today (BAA-20-100-SOL-0002, AOI #4.1C: Diagnostic Assay for detection of COVID-19 disease). (b)(5)
(b)(5)
Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.
In addition to the lab system, reagents and consumable /single use disposable materials will be provided separately as individually pouched kits capable of supporting two assays. The kits will be packaged as multiples in cartons designed for transportation an use in field deployed scenarios.
We are highly dedicated to doing all that we can to support the immediate needs of potential COVID-19 patients and the containment strategies associated.
Best wishes and keep safe,
Liam

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From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,
Thank you very much for your letter. I appreciated having the opportunity to hear from you on today's call. I am copying my Chief of Staff, Keagan Lenihan, who will follow up with you.
Steve

From: Vincent Forlenza <vincent_forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

<image001.png>

Vincent A. Forlenza
Executive Chairman

BD
1 Becton Drive, Franklin Lakes, NJ 07417 USA MC: 097
Office: 201-847-7306 Fax: 201-847-5361
Email: Vincent.Forlenza@bd.com Website: www.BD.com

Corporate Headquarters Mailing Address: BD (Becton, Dickinson and Company) 1 Becton Drive Franklin Lakes, NJ 07417 U.S.A.

<Sterigenics response March 25 2020.pdf>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/27/2020 11:34:06 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
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For exec sec

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Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

BD

Vincent A. Forlenza
Executive Chairman

BD
1 Becton Drive, Franklin Lakes, NJ 07417 USA MC: 097
Office: 201-847-7306 Fax: 201-847-5361
Email: Vincent.Forlenza@bd.com Website: www.BD.com

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/27/2020 11:47:27 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: SH Materials for Today
Attachments: CTAP One-Pager 03272020 1145am.docx; WH Presser TPs 03272020 1144am.docx

Hi Dr. Hahn –

Attaching updated CTAP one-pager and WH presser TPs to remov **(b)(5)**

Thanks,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell **(b)(6)**
michael.felberbaum@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Felberbaum, Michael
Sent: Friday, March 27, 2020 11:00 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: SH Materials for Today

Hi Dr. Hahn –

Attached are a few materials for today.

- CTAP One-Pager for your meeting with Jared/Hope
- WH Presser TPs on CTAP and Convalescent Plasma/Hyperimmune Globulin
- Topline Responsive Language for use as needed (this is an updated version of the document Stephanie has been preparing)

Please let us know if you have any questions or need anything else.

Thanks!

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell (b)(6)
michael.felberbaum@fda.hhs.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/27/2020 12:11:27 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: PETER PLEASE SEE ASAP: Comms for Today
Attachments: WH Presser TPs 03272020 1206pm.docx

It is Texas. Peter confirmed and he has small edits to the presser. Michael will send you clear copy.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, March 27, 2020 12:08 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: PETER PLEASE SEE ASAP: Comms for Today

Dear Michael,

Very minor edits. Let's just stick with Texas for today. Thanks. (with attachment)

Best Regards,
Peter

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, March 27, 2020 12:00 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: PETER PLEASE SEE ASAP: Comms for Today
Importance: High

Hi Peter –

From what I understand from the AEG call, **(b)(5)** have removed from Dr. Hahn's WH talking points – and we need to remove from the press release as well, correct?

Also he said you had mentioned that the **(b)(5)**

(b)(5)

Can you please weigh in ASAP so we make sure he has what he needs?

Thanks!

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell (b)(6)
michael.felberbaum@fda.hhs.gov

U.S. FOOD & DRUG
ADMINISTRATION

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/27/2020 8:48:18 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: CMS Call Talkers
Attachments: Draft Remarks SH Doctors call.1 20020328.docx

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/28/2020 9:21:01 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; 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: SH For Review- Media Statement- COVID-19 Supply Chain Update

Thx

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: March 28, 2020 at 9:12:30 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: SH For Review- Media Statement- COVID-19 Supply Chain Update

We can make that change and proceed. TY.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 28, 2020 9:12 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: SH For Review- Media Statement- COVID-19 Supply Chain Update

Looks good. Do you thin **(b)(5)**

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: March 28, 2020 at 8:01:00 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: SH For Review- Media Statement- COVID-19 Supply Chain Update
Importance: High

Sir
Attached is your statement on supply chain updates. We could put this out today or Monday depending on your availability to clear. It has gone through the entire clearance process. Laura

FDA STATEMENT

FOR IMMEDIATE RELEASE

(b)(5)

(b)(5)

(b)(5)

Additional Resources:

- FDA: Coronavirus Disease 2019 (COVID-19)
- Drug Shortages
- Biologics Shortages
- FAQs on Diagnostic Testing for SARS-CoV 2

###

Media Contact: Jeremy Kahn, 301-796-8671
Consumer Inquiries: Email or 888-INFO-FDA

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 3/28/2020 11:45:11 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Please View: TP's Updated: Talking points for Dr. Hahn's CMS call tomorrow.
Attachments: 1200-1-Remarks-CMS-SH Doctors call.1 20020328.docx

Importance: High

OEA is providing another update, the talking points attached should be used instead. Sorry, not sure why these are coming in moments before you need to dial in.
Flagging high importance to help ensure you can be sure to see this email.

From: Olivarria, Frank
Sent: Saturday, March 28, 2020 11:25 AM
To: Hahn, Stephen (SH1@fda.hhs.gov)
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Colin Rom (Colin.Rom@fda.hhs.gov) <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan; Anand Shah (Anand.Shah@fda.hhs.gov) <Anand.Shah@fda.hhs.gov>
Subject: Additional Document: Talking points for Dr. Hahn's CMS call tomorrow.

OEA forwarded the following, just this morning – and they have requested that you be provided a copy for your call. Dial-in is at 11:45 AM – will text dial-in number as we get closer.

Frank

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Saturday, March 28, 2020 10:34 AM
To: Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>; Nikolov, Nikolay <Nikolay.Nikolov@fda.hhs.gov>
Subject: RE: Talking points for Dr. Hahn's CMS call tomorrow.

Frank can you attached to calendar?

From: Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Sent: Saturday, March 28, 2020 10:24 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rebello, Heidi

<Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>; Nikolov, Nikolay <Nikolay.Nikolov@fda.hhs.gov>
Subject: RE: Talking points for Dr. Hahn's CMS call tomorrow.

And attached are recently cleared Master Talking Points for you as well.

Dayle Lewis Cristinzio
Director, Stakeholder Engagement
Office of External Affairs
U.S. Food and Drug Administration
(t) 301.796.8898 | (m) **(b)(6)**
dayle.cristinzio@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Saturday, March 28, 2020 9:01 AM
To: Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>; Nikolov, Nikolay <Nikolay.Nikolov@fda.hhs.gov>
Subject: RE: Talking points for Dr. Hahn's CMS call tomorrow.

Hi Dayle –

Thanks to you and your team for organizing all of this and making it truly a joint event. I've attached some additions to my comments, **(b)(5)** The language is from one of our recent PR (3/16 I believe) so should be cleared to use – tracked edits at the very end.

Anand

From: Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Sent: Friday, March 27, 2020 8:25 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Murray, Jeffrey S <Jeffrey.Murray@fda.hhs.gov>; Nikolov, Nikolay <Nikolay.Nikolov@fda.hhs.gov>
Subject: FW: Talking points for Dr. Hahn's CMS call tomorrow.

Anand –
Please find attached your draft remarks for tomorrow's call. You will note, Dr. Hahn's remarks are also included in this document. I haven't received the dial in number for the speakers line yet, but will forward as soon as I do. Speakers are

asked to **dial in at 11:45 a.m. tomorrow** to ensure the operator has time to check everyone in before the call begins at noon.

Also attached is the draft run of show, with more details on the timing of the discussion.

Also of note, FDA is providing three experts for the panels. I've cc'd them on this message for awareness. Thanks for agreeing to join on short notice.

Debra Birnkrant, Director of the Division of Antiviral Products (DAVP)
Center for Drugs, Evaluation and Research

Jeffrey Murray, Deputy Director of the Division of Antiviral Products (DAVP)
Center for Drugs, Evaluation and Research

Nikolay Nikolov, Associate Director for Rheumatology
Division of Pulmonary, Allergy and Rheumatology Products (DPARP)
Center for Drug Evaluation and Research

Email invitations sent to physicians included the following language. Below dial in is for physicians/invited participants. NOT SPEAKERS.

On behalf of CMS Administrator Seema Verma, FDA Commissioner Stephen Hahn, MD, and the White House Coronavirus Task Force, I am writing to invite the physician membership of your organization to the next call in our new series for physicians: **Lessons from The Front Lines: COVID-19**. The call will take place on **Saturday, March 28th from 12:00 PM – 2:00 PM EST**, and the topic of discussion is: **COVID-19 Therapeutics**. We invite you to join us to share your ideas, strategies, and insights with one another.

Please see dial-in details below. Conference lines are limited, so we highly encourage you to join via audio webcast, either on your computer or smartphone web browser.

Participant Dial In: 877-251-0301
Conference ID: **(b)(6)**
Audio Webcast **(b)(6)**
(b)(6)

Dayle Lewis Cristinzio
Director, Stakeholder Engagement
Office of External Affairs
U.S. Food and Drug Administration
(t) 301.796.8898 | (m) **(b)(6)**
dayle.cristinzio@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/28/2020 1:49:10 PM
To: Katz, Mitchell [Mitchell.Katz@nychhc.org]
Subject: Re: is there a way to get other countries to produce convalescent serum?

Mitch
Are you all using convalescent plasma in NY? We set up/allowed/provided guidance about this starting earlier this week using a compassionate use process. Our plan is to move next week to an expanded access protocol?

We're working on identifying donors so I'll pass along your suggestion to the team. Mitch, you are doing great work. Please take care.
Steve

From: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Date: March 28, 2020 at 12:41:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: is there a way to get other countries to produce convalescent serum?

Steve, hope you are hanging in. Things are pretty desperate here. We are using (b)(4) more ventilators today than yesterday for covid and we are only (b)(4) of hospital capacity.

The countries that are recovering abroad from this pandemic, especially china, seem like they would have capacity to produce convalescent serum and ship to US.

I don't know that this is a FDA issue. I know companies normally come to you to ask for licensing their product but could you give me any advice on how US could encourage this to happen.

Thank, Mitch

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/28/2020 2:22:18 PM
To: Katz, Mitchell [Mitchell.Katz@nychhc.org]
Subject: RE: is there a way to get other countries to produce convalescent serum?

Do you have time for a quick call?

From: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Date: March 28, 2020 at 2:02:03 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: is there a way to get other countries to produce convalescent serum?

Yes thanks to your guidance we are setting it up in NYC health and hospitals. Mt Sinai already doing it. I am thinking though that our ability to identify people who are immune and have antibodies and do the plasmapheresis will likely limit application. If a country that was over the bad part of the epidemic could be brought into service for money it might save lives.

Appreciate any suggestions your team has. Thanks for being so responsive. mitch

---

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Saturday, March 28, 2020 1:49 PM
To: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Subject: Re: is there a way to get other countries to produce convalescent serum?

Mitch
Are you all using convalescent plasma in NY? We set up/allowed/provided guidance about this starting earlier this week using a compassionate use process. Our plan is to move next week to an expanded access protocol?

We're working on identifying donors so I'll pass along your suggestion to the team. Mitch, you are doing great work. Please take care.
Steve

From: Katz, Mitchell <Mitchell.Katz@nychhc.org>
Date: March 28, 2020 at 12:41:07 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: is there a way to get other countries to produce convalescent serum?

Steve, hope you are hanging in. Things are pretty desperate here. We are using (b)(4) more ventilators today than yesterday for covid and we are only (b)(4) of hospital capacity.

The countries that are recovering abroad from this pandemic, especially china, seem like they would have capacity to produce convalescent serum and ship to US.

I don't know that this is a FDA issue. I know companies normally come to you to ask for licensing their product but could you give me any advice on how US could encourage this to happen.

Thank, Mitch

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 3/28/2020 2:26:52 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: task force 3/28
Attachments: 2020.03.28 WHTF.docx

Attached is task force briefing doc

From: Doug S (b)(6)
Sent: 3/28/2020 10:53:51 PM
To: mikepence@whitehouse.gov
CC: KTLA [ktla@ktla.com]; AAD President [president@aad.org]; KevinMD Plus [newsletter@kevinmd.com]; Association of American Physicians and Surgeons Jeremy Snavely [aaps@aapsonline.org]; Physicians Grassroots Ama [grassroots@ama-assn.org]; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e55e9a27325472887051a2c7f4f2f88-Commissione]
Subject: COVID-19 treatment 80 more patients
Attachments: COVID-IHU-2-1.pdf; ATT00001.txt

Double blind studies right now would be immoral.

Would you really rather have the placebo?

Start treatment early.

Douglas A Smith MD MPH

PLEASE READ & PASS ON

https://www.mediterranee-infection.com/wp-content/uploads/2020/03/COVID-IHU-2-1.pdf

From: Shaq Abid [ceo@sagaciousdiagnostics.com]
Sent: 3/29/2020 5:56:48 AM
To: Langevin, Helene M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9c18f6030f4317b860058c8d25fae8-HHS-helene.]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Lowy, Douglas R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=573f83e4718445c6b76f6fac82aa5d5a-HHS-LowyD-m]; michael.strong@cihr-irsc.gc.ca; Azar, Alex (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4db7abd56a7e478883f5cd8e2e8a18d3-HHS-Alex.Az]; Beaver, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82282cb5fd5e452fabe98079c5f09721-BEAVERJ]; Ibrahim, Amna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=998ae13342184012b629b9a35da4fed7-IBRAHIMA]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; CDER EUA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=686f4eba497a4b6193a928a34b7a877d-CDER EUA]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; Biable, Missiratch (Mimi) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7bbed7a97e345998984abd6ff86ccf7-BIABLEM]; Keegan, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ba5139441a2487d91be88ac90569ee4-KEEGANP]; Kelly, Halonna R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32af50df84fb4d2bab8ed0b162c52cac-HHS-halonna]
Subject: [5 minute] science class for government people

Here is a synopsis of the paper released in the last few days.

https://www.medrxiv.org/content/10.1101/2020.03.25.20043489v1.full.pdf

UV Sterilization of Personal Protective Equipment with Idle Laboratory Biosafety Cabinets During the Covid-19 Pandemic

A group at the University of Nebraska Medical Center recently developed a protocol to sterilize N95 respirators using UVGI.12

Specifically, they subjected used N95s to 60 mJ cm−2 of UV-C radiation (254 nm)—which exceeded the estimated sterilization dose of 2-5 mJ cm−2 for single-stranded RNA by several-fold—by stringing them across a room containing two UVGI towers on either side. The UVGI doses were remotely monitored using a UV meter to ensure proper sterilization.12

Unfortunately, not all hospitals are equipped to set up dedicated rooms for decontamination or possess the specialized UVGI towers that are outlined by Lowe et al.12

On the other hand, many university-affiliated hospitals and higher academic laboratories have access to biosafety cabinets (BSCs) that are regularly used in research to sterilize laboratory equipment via UV-C light.

-

https://www.medrxiv.org/content/10.1101/2020.03.22.20040923v1.full.pdf

Yale researchers, determined the majority of Urgent Care Center do not have testing capabilities

Scarce COVID-19 Testing Capabilities at Urgent Care Centers in States with Greatest Disease Burden

Although this study could not definitively define test fees, most UCCs stated they would charge test fees, contrary to recent federal regulations, in addition to fees for the urgent care visit itself as of March 20.

Of 250 UCCs contacted, 57 (22.8%) offered COVID-19 testing.

53 (94.6%) UCCs charged a visit fee in addition to the COVID-19 lab test fee. For the 49 centers that provided the wait time for test results, the median time was 120 hours (interquartile range 96 hours to 144 hours).

-

The potential SARS-CoV-2 entry inhibitor

In this study, we discovered that theaflavin showed the lower idock score (idock score: −7.95 kcal/mol). To confirm the result, we discovered that theaflavin showed FullFitness score of -991.21 kcal/mol and estimated ΔG of -8.53 kcal/mol for the most favorable interaction with contact area of SARS-CoV-2 RBD by SwissDock service.

Our results suggest that theaflavin could be the candidate of SARS-CoV-2 entry inhibitor for further study.

https://www.biorxiv.org/content/10.1101/2020.03.26.009803v1

[**Alchemist's note**: Again the implication here is all the hospital workers, should be drinking green or black teas as a prophylactic measure.]

-

Analysis of adaptive immune cell populations and phenotypes in the patients infected by SARS-CoV-2

https://www.medrxiv.org/content/10.1101/2020.03.23.20040675v1.full.pdf

. We showed that upon infection, lymphocyte percentage declined, the percentages of CD4 and CD8 T cells within the lymphocyte population remained unchanged, and B cell percentage was relatively increased. CD4 and CD8 T cells exhibited a mild and strong activation phenotype, respectively. Notably, the percentages of Tfh- and GCB-like cells increased. Similar phenotypes among the patients in various age groups indicate that aged individuals are also capable to respond to SARS-CoV-2 infection. Our data support the notion that adaptive immunity could be normally activated and defend against SARS-CoV-2 infection.

Elderly individuals typically exhibit a reduction of the lymphocyte population and weaker ability to defend against viral infection

Lymphopenia was shown in COVID patients from previous studies

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/29/2020 5:16:49 PM
To: Mario Diaz-Balart; (b)(6)
Subject: COVID-19 research material for your review and input
Attachments: International Journal of AntiMicrobial Agents.pdf; Letter from Dr. Zelenko.pdf

Dear Congressman Diaz-Balart,

(b)(6)

The FDA remains steadfast in our commitment to public health, now more than ever. We are on the front line, working at all level of our U.S. government, to do everything we can in the war against COVID-19, especially by aggressively facilitating the development of medical products to diagnose, prevent and treat this virus.

President Trump personally asked me to share with you the attached research material for your review and input:
1.) Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an openlabel non-randomized clinical trial, to be featured in an upcoming International Journal of AntiMicrobial Agents (1st attachment);
2.) A personal letter from Dr. Vladimir Zelenko, of Monroe, NY, to the Israel Ministry of Health, recommending an outpatient treatment protocol for certain COVID-19 patients involving the medicines hydroxychloroquine, azithromycin and zinc sulfate (2nd attachment); and
3.) Information for Clinicians on Therapeutic Options for COVID-19 Patients, from the CDC's website: https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html.

I hope your family and loved ones are staying well.

Sincerely,
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/29/2020 6:33:47 PM
To: Rand Paul (b)(6)
Subject: Re: COVID-19 research material for your review and input

Senator Paul,

(b)(6)

Best
Steve

From: Rand Paul (b)(6)
Date: March 29, 2020 at 6:05:30 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: COVID-19 research material for your review and input

(b)(6)

Sent from my iPhone

On Mar 29, 2020, at 4:16 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Dear Senator Paul,

(b)(6)

The FDA remains steadfast in our commitment to public health, now more than ever. We are on the front line, working at all level of our U.S. government, to do everything we can in the war against COVID-19, especially by aggressively facilitating the development of medical products to diagnose, prevent and treat this virus.

President Trump personally asked me to share with you the attached research material for your review and input:
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2. A personal letter from Dr. Vladimir Zelenko, of Monroe, NY, to the Israel Ministry of Health, recommending an outpatient treatment protocol for certain COVID-19 patients involving the medicines hydroxychloroquine, azithromycin and zinc sulfate (2nd attachment); and
3. Information for Clinicians on Therapeutic Options for COVID-19 Patients, from the CDC's website: https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html.

I hope your family and loved ones are staying well.

Sincerely,
Steve
<International Journal of AntiMicrobial Agents.pdf>
<Letter from Dr. Zelenko.pdf>

From: ssharma19.excite [(b)(6)]
Sent: 3/29/2020 8:38:10 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: COVID-19 test

Dear Dr. Hahn,

My name is Sanjeev Sharma, MD, from Oceanside, California.

My network and associates have available to us a rapid COVID-19 diagnostic test, from Xiamen Biotime, a Chinese company. This test has been validated by Chinese clinical trials, as well as millions of real time uses in China, South Korea, Japan, and Germany. It is an IgG and IgM immunoassay, obtaining excellent correlation with the RNA-PCR.

We are asking for emergency FDA approval to use this test.

As you are well aware, the situation on the ground here is critical.

I hope and pray you and yours are safe and healthy.

Sincerely,

Sanjeev Sharma, MD

(b)(6)

From: (b)(6)
Sent: 3/29/2020 10:43:47 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Covid19 Fast Track wellness solution

Dear Stephen,

I was exposed to Covid-19 and the below solution worked for me to turn the exposure into a vaccine. I share it with you to benefit you and anyone else who it could help.

Tested it again today after 8 days of isolation and it worked.

Covid-19 came from snakes.
I asked a pharmacist with experience in three U.S. states who also travels globally what the do for snake bites.
I researched a variety of sources.

This is what worked:
1. social isolation
2. washing hands
Yes prescriptions used for HIV and malaria is needed for serious cases.
I was only exposed to the Covid-19 virus.
Had zero symptoms other than 30minutes after exposure and only for 24hours.
The symptom I had was it felt tightness on the heart and lungs.
Immediately cancelled all appointments.
3. Turning exposure of the virus into a vaccine and helping your body fight the virus.
i) hydrogen peroxide:water mouth wash
1:8. It immediately released the pressure to the heart and lungs.
ii) high doses of vitamin C to strengthen the immune system
I used 3x1000mg the first day and 1000mg/daily after that.
I am 5'4" and 140lbs. A larger man would need more. A child less. It must be a high doseage or the virus will become stronger.
iii) cleansing the digestive system with water and specific herbs that counteract the snake venom. Madagascar cloves worked for me.
Took two very high potency shots of water and cloves 1 day. This was all I needed but I've only been exposed and otherwise take zero medication. For someone who takes medication they would need 3 days of shots. The shots must be very concentrated.

Chose Madagascar cloves because I researched globally where people were successfully resistant to the virus.

Thank You,

(b)(6)

From: hellen wang (b)(6)
Sent: 3/30/2020 12:59:31 AM
To: Arnone, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3249bca5836c4d1bb9d051eee85026b2-James.Arnon]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; marcia.madrigal@fda.gov; Lewis, Debra * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c279213150d4c72ba7381cfb56ebaec-Debra.Lewis]; brenda.boateng@fda.gov; steve.toigo@fda.gov; christine.rynkiewicz@fda.gov; Wooten, Toni V [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b63a745ca45401dad3dac4ef05ce7dd-TWOOTEN]; joan.gotthardt@fda.gov; Benz, Daniel A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de24adc8414e4ffa8926921c317a44f8-DBENZ]; linda.grassie@fda.gov; phillip.osborne@fda.gov; Krantz, Zoe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3781bbde81cf486d9f2447ff29ddedb3-ZKrantz]; Anderson, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=445ffa79c5f847c582d792b730829f34-Amy.Anderso]; mary.hitch@fda.gov; Burkholder, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d5fda60a4814bd290d84bd28a2a9292-BBURKHOL]; susan.hight@fda.gov; john.harshman@fda.gov; Beaulieu, Andrew J* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99772588da104f83a39ab2742c962f81-ABEAULIE]; zoe.gill@fda.gov; lonnie.luther@fda.gov; Bataller, Neal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2458a8e78711449395cdc90423c00a6c-NBATALLE]; Dunham, Bernadette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c09660765a164cb9988e6fe505b8286c-Bernadette.]; pam.scott@fda.gov; robert.ottaviano@fda.gov; david.newkirk@fda.gov; Strambler, Karen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9e7f400f70b4e3eaa22acf93adb82b8-KStrambler]; Milone, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7fa181e8bdff495e8a2ad3d9c4669408-JXM2]; Smith, Michelle A (CFSAN) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccd9c9b7353949b1b78b01b57988b7b1-MAS8]; george.graber@fda.gov; Cheng, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f44e11612254a8296baf31efef62e4f-John.Cheng]; edmond.baratta@fda.gov; Clarke, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09ecd711173a4e3db920ef6786f5bfd3-ACLARKE]; linda.wilmot@fda.gov; Buckler, Wendy S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35f9c40840524cac8ff494ddd5ba7b64-WBUCKLER]; cynthia.polit@fda.gov; marc.hess@fda.gov; melanie.berson@fda.gov; Hungerford, James M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=200f87222ae04feb9299fbd2497ea375-James.Hunge]; mark.schmall@fda.gov; Anderson, Chanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b670a6f99ca4f1b8fd22a826feb4a25-Chanda.Ande]; Jansen, Darren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db3fd2f194e74e2bb89521b803e95f1a-Darren.Jans]; McMillian, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dfd4045d00e4b18a0f789f79b0cd954-Carolyn.McM]; daniel.benjamin@fda.gov; james.bona@fda.gov; stephanie.magill@fda.gov; mary.poos@fda.gov; keith.webber@fda.gov; Dubbin, Eric S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ca35a5c26754a94936ccc2ba454e994-EDUBBIN]; mary.brady@fda.gov; linda.webb@fda.gov; burt.pritchett@fda.gov; michael.owen@fda.gov; drugs@fda.gov; BadAd [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8a8162002ed4a62b571fc8f798de298-BadAd]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]; FDA FURLS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f2f79b4501e4502a5e6017630ad139b-FDAFURLS]; Industry.Biologics [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77a373c811df4854971fd642ebfdb54b-Industry.Bi]; OC Combination

Products [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dec648ce1a84825910b2937ab184359-combination]; CFSAN-Industry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15041aa2290245fba3c546faa0dd7b80-CFOCO3]; CFSAN-Consumer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2e241981934400f8bd471c0b7cc790f-CFOCO2]; Dhingra, Amber [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4c59af3c1b94561b71ef1df7bf30d45-Amber.Dhing]; richard.ruby@fda.gov; Anderson, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a14bbd7f14904c0cb95dbca1aba03478-Ellen.Ander]; ming.zhang@fda.gov; donald.vasbinder@fda.gov; poppy.kendall@fda.gov; jjohannessen@fda.gov; aborja1@fda.gov; janet.mcdonald@fda.gov; amber.jessup@fda.gov; r.fillmore@fda.gov; Abel, Greg A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866c3daebc04247885b27b8ab6b1207-GABEL]; ldavis3@fda.gov; davidnewkirk@fda.gov; agreene4@fda.gov; Farmer, Laurie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acefb9e6ed444fa7bd4d33e41bbcc9d1-LFARMER]; Williams, Nikol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=050980e4dd7c418f92602551a2720d0d-Nikol.Willi]; joinourteam@fda.gov; deputy.commissioner@fda.gov; Quick Questions [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28d5d6a0a74a486e812e6519ee632e66-quickquesti]; FDA Vendor Payments Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e52ff1207b74fc986cc7a8b01565364-FDAVPT]; judith.summers-gates@fda.gov; McGee, Ed [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38501f7129c4c3ba5c348bf14f7508c-EMcgee]; sarahsellers@fda.gov; mhamburg1@fda.gov; PatientAffairs [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e54d502c86a3456d81a85a39c316ffe1-PatientAffa]; trye6@fda.gov; vavaritt@fda.gov; psnews@fda.gov; consumers@fda.gov; llong2e@fda.gov; patientmedicationinformation@fda.gov; pkendall@fda.gov; Hartogensis, Martine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02df91d554d34b948fc58433d0e42073-MHARTOGE]; IT Call Center [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52004b7b3273475c92991e094476fa65-ITCallCente]

Subject: Be prepared for Wuhan Virus or Any Chinese Communist Party virus !

Attachments: wuhanvirus_biotechweapon.pdf; letterto(b)(6)Governor_1.pdf; Letterto(b)(6)Governor_2.pdf

Dear All

My name is Hong Wang, I am **(b)(6)** citizen and a Falun Gong practioner. As you know, Falun gong is a mind body practice based on truth, compassion and forbearance. It has been spread in more than 80 countries in the world and has brought great improvements in health and fitness for millions of people in the world. Unfortunately, it has been persecuted in China since 1999.

I have been living in **(b)(6)** ever since I came to USA. It is pretty much my second hometown, especially it provide me the freedom to continue practice falun gong when the persecution in China started. I really want to contribute back to **(b)(6)** USA as well.

Currently the entire **(b)(6)** has been affected by coronavirus from Wuhan. Majority people stay at home, scared, etc. As you may know, traditional Chinese Medicine differ vs west medicine, it focus on prevent disease as 1st step. Contagious disease in Chinese medicine is consider that the evil qi (邪气) is strong and thus caused issue. What need to do is to improve positive righteous qi （正气）. In addition, I also know that 70% of a person's heath is related to his spirit and mind, in Chinese it is called 七分精神三分病.

I understand that people currently all put their hope on vacancies, on new medicine, etc. I have been reading reports in Chinese ever since this pandemics and plagues happened including reports from anatomy. This virus not only attack lung, but also multiple organs and cause damage to immune system. It is more like SARS + AIDS https://www.medsci.cn/article/show article.do?id=75aa189e8675. People died more like drown in the water : Lack of Oxygen because the entire lung is full of phlegm.

As you probably already know, there is really no any cure for virus in theory, especially for virus attack lung or multiple organs (not mainly in blood) . All methods are just help inhibit virus replication or improve immune system. I use flu as an example and you could see this year Flu data. In addition, virus mutated all the time and we have seen reports on mutation change for the Wuhan virus (same data indicate Flu virus changes the time to time too, it is one explanation why vaccine not always work though.) This does not include the development time for a new vaccine.

I also attached my letter on urge government to investigate the origin of coronavirus from Wuhan. To my knowledge it is biotech weapon since no way a virus in bat could automatically mutated with exactly same change as a virus from human lab. There are quite a lot of same discussion in the internet too. As you could see what CCP did to Falun Gong practioners . People are quitting CCP. CCP is struggling for their control and I believe that they could do the same evil things to anyone to maintain their power. The world needs to be prepared for that!

Therefore in this extremely time, I would think to help to improve immune system of people on their own, improve their mind (strong mind) is very important. A person's moral stand all related to its righteous qi （正气）.

I recommend you one story from an England small city called Todmorden, they start to change their home by plant in local and this even spread to the world, https://www.youtube.com/watch?v=4KmKoj4RSZw&t=41s

Currently a lot of people stay at home, they need eat and also need to find something positive to do and educate kids as well.

I know **(b)(6)** is suitable to plant all kind of foods. Chinese parents live in **(b)(6)** **(b)(6)** produce a lot of different vegetables each summer on the land / soil provided by **(b)(6)** When I was a Child, my parents brought me to plant together with them. Now I recall that is really a wonderful family time plus I learned a lot of knowledge from plant different vegetables.

I also recommend one simple easy plant vegetables that could help improve positive energy (阳气) : garlic chives, Chinese chives https://en.wikipedia.org/wiki/Allium tuberosum. Chinese people use it to make dumplings or mix with eggs. Actually all different kinds of vegetables helps. The vegetables had a little smell does help more though.

If you look back of what Wuhan residents has been through, you will see how important food are ! None of them knew that one day they even short of food before the city blocked.

Soil (earth) is the gift from heaven, in Chinese it is called Mother for all. In ancient China, emperor respect heaven and respect earth. If you go to Beijing, you will see Temple of Heaven and Temple of Earth. Ancient Chinese story also consider getting soil is the sign for gain the country ☺

Definitely mediation Falun Dafa could help to improve immune system as well. I started practice Falun Gong since **(b)(6)** and other than the time I **(b)(6)** I did not see health physician for over 20 years, and I know I am not alone. You could find enormous stories including mainland China own newspaper reports before persecution at http://en.minghui.org/cc/17/. All falun dafa activity are free to anyone and you could find book and videos at www.falundafa.org

If big business and government and congress encourage their employees to change first, it will for sure to lead movement for the entire society. I hope with your help, business, congress, and government could work together to promote positive energy (and still could be home event if needed) for current situation.

Ancient Chinese people believe pandemics and plagues are punishment from heaven. Normally King and citizens will repent to the divine with all due sincerity, admit to their faults, and pray for a chance to change their ways. I attached the article "Three Plagues in the Ancient Roman Empire" http://en.minghui.org/html/articles/2020/2/4/183093.html for your reference.

I believe history is mirror for today. Chinese Communist Party (CCP) has been persecuted innocent Falun Dafa practioners for more than 20 years now. And not only to Falun Gong practioners, have CCP been doing evil things to all, such as Christians, Tibet, XiJiang, and this time the Wuhan virus. CCP destroyed the glory of Chinese traditional culture. Isn't it should be punished and be weeded out by God? I am sure anyone who are still siding with it for sure will have bad fortune. And currently those countries and cities who has severe infected numbers, if you check they are all close to CCP, for example Italy is the first country for China's The Belt and Road Initiative in Europe. For your safety, be away from the CCP and stop siding with it!

I wrote to **(b)(6)** before. I attached my letter to them too to see whether you are interested to help. I learned a lot after follow Formal Governor **(b)(6)** :)

Thank you for taking your time to read my letter.

Sincerely

Hong Wang

P.S, I recommend below info for you :

Is There a Magic Cure for the Coronavirus?
http://en.minghui.org/html/articles/2020/2/26/183410.html

Is There a Golden, "Sure-Fire" Cure for an Epidemic?
http://en.minghui.org/html/articles/2020/2/4/183091.html

how ancient Chinese view on virus disease
https://www.youtube.com/watch?v=ISgHk6fTSwo&feature=youtu.be&fbclid=IwAR2AvCk6PXKZvWOBtIfjZ21fm7g cLntzl5bB9a098ccHmbQYg33gPhvVDA

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 7:08:22 AM
To: McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Tyler, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddb047ff73e640b29259d7ca22611e67-James.Tyler]; Tootle, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0900da296e4a474da740ef1c47e6f1bd-William.Too]
Subject: RE: Background for your 8:30

Thanks, Maren

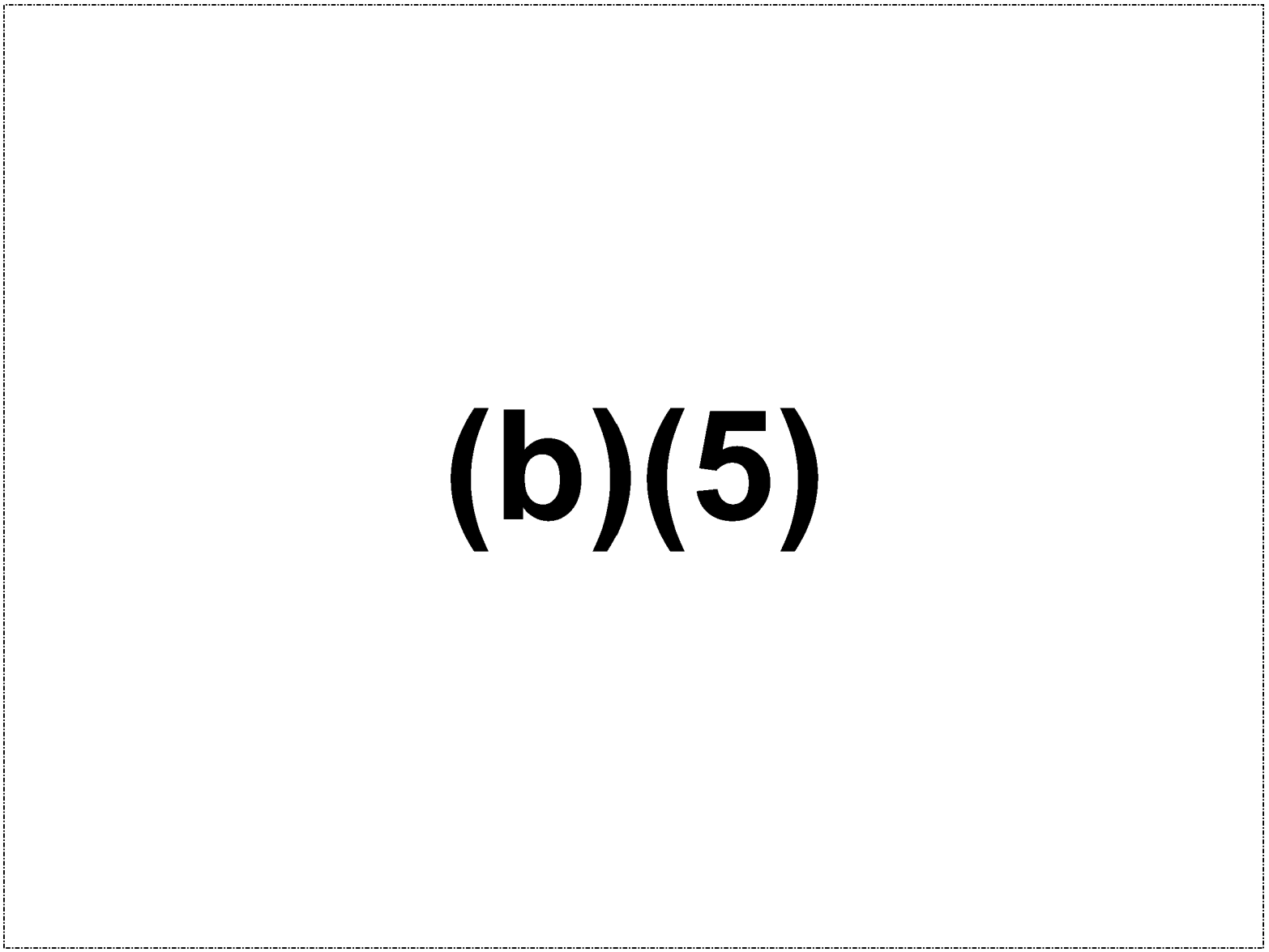
From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Date: March 29, 2020 at 11:38:16 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>
Subject: RE: Background for your 8:30

Shortened version!

Below is some funding background for your meeting with the Secretary tomorrow at 8:30 on the Supplemental. Overall,

(b)(5)

(b)(5)


(b)(5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 7:08:44 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Background for your 8:30

Let's put this on our agenda for today.
Thanks
S

From: McBride, Maren <Maren.McBride@fda.hhs.gov>
Date: March 29, 2020 at 11:38:16 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>
Subject: RE: Background for your 8:30

Shortened version!

Below is some funding background for your meeting with the Secretary tomorrow at 8:30 on the Supplemental. Overall,

(b)(5)

(b)(5)

(b)(5)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 3/30/2020 7:09:26 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: for SH review: diagnostic stmt, CNN oped
Attachments: diagnostics statement.3.30.7am_jeff.docx; Hahn coronavirus op-ed CNN 3.30.docx

Morning sir!

For your review

- Diagnostics statement: we will issue this AM, just want to give you another chance to look at it, if you'd like. Attached reflects latest edits from Anand, Jeff.
- CNN oped. We've gone back and forth with CNN a couple of times. The attached reflects the latest edits. This may go online today if you are ok with it

Stephanie Caccomo
Press Officer

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

From: Brian Colton (b)(6)
Sent: 3/30/2020 7:22:03 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Use of Hydroxychloroquine vs Doxycycline

G6PD deficiency patients can't tolerate the use of Quinines. During Operations Desert Shield and Storm we issued Doxycycline to deploying persons to eliminate the need for G6PD testing. I strongly recommend the use of Doxycycline instead of Hydroxychloroquine with Azithromycin. The PDR states the co-administration of Hydroxychloroquine and Azithromycin be avoided. However, co-administration of Doxycycline and Azithromycin is acceptable. I came into close contact with Chinese tourists at a buffet restaurant in late December and developed a mild Pneumonia diagnosed by x-ray. I was prescribed Doxycycline and it cleared the Pneumonia but I was still ill with head and chest congestion and extreme phlegm and mucus. I returned to Urgent Care and was given Azithromycin and was cured at the end of this treatment. I also believe Doxycycline may be beneficial to first responders and health care high risk persons as a prophylaxis against COVID-19. I've emailed this information to Governor Cuomo, President Trump, Surgeon General Adams, and Dr David Boulware conducting clinical trials in Minnesota. I encourage the testing of both Hydroxychloroquine and Azithromycin on non-G6PD deficiency and Doxycycline with Azithromycin on G6PD deficiency patients. If Doxycycline works as well, switch to Doxycycline to eliminate the need for G6PD testing. Thank you for your time!

From: Ralph Brendle [ralph@rvrbend.com]
Sent: 3/30/2020 9:40:59 AM
To: surgeongeneral@hhs.gov; anthony.fauci@nih.gov; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: Dean Robert (b)(6) Bernard Wolff [bwolff@chromasol.com]
Subject: Coronavirus Possible Cure (b)(4) rom Ralph Brendle
Attachments: (b)(4) Presentation - Feb 2019.pdf (b)(4) Letter To Mike Pence.doc

Dr. Stephen Hahn, Dr, Anthony Fauci, & Dr. Jerome Adams,

Attached is a letter that I have been trying to get to VP Mike Pence and his team since this past week. This could be a possible cure for the Covid 19 virus. Please contact me as soon as possible so that I can provide you the person who developed this product and who can provide you all the samples that you will need for testing.

Thanks,

Ralph Brendle
RIVER BEND
Sportsman's Resort
(800) 516-9606
Cell (b)(6)
ralph@rvrbend.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 12:19:19 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Sterigenics Sterilization Capacity urgently needed
Attachments: Sterigenics response March 25 2020.pdf

Is there any update?

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

Thank you for your continued efforts on behalf of patients as we continue to combat COVID-19.

I will be brief, the response from Cobb County has been very disappointing. They are only allowing for a limited reopening of the Sterigenics facility and for the sterilization of PPE only. We need sterilization capacity for critical Medical Devices and we need it immediately.

I respectfully ask you and your team to revisit the discussion with Cobb County. I attach the response from Sterigenics for your reference.

Thanks again for your help,

Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: (b)(6)
E: liam.kelly@teleflex.com

Teleflex
550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: Liam Kelly <liam.kelly@teleflex.com>
Date: Wednesday, March 18, 2020 at 8:37 AM
To: "Hahn, Stephen" <sh1@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Dr Hahn,
Thank you for your attention to the sterilization issue. This will assist companies like Teleflex who are seeing increased demand for products needed to treat COVID-19 patients. Without this capacity we may have a supply issue which could impact patient care. It is in times of crisis that almost always brings out the best in people, companies and agencies. We should learn and make it every day life!

On a separate but related topic, I would like to make you aware of an effort that Teleflex is working on pertaining to a Point of Care, fully portable solution for the rapid identification of the presence of the novel coronavirus in respiratory secretions. We are in contact with BARDA and are submitting an application later today (BAA-20-100-SOL-0002, AOI #4.1C: Diagnostic Assay for detection of COVID-19 disease). **(b)(5)**

(b)(5)

Unlike the present solutions where samples are collected remotely and then transported to a central lab facility where the molecular assay is performed, our intention is to greatly reduce the overall process time by elimination of the sample transportation interval. Our intention is to provide a means of performing a highly sensitive assay at the time and place of sample collection. The system will consist of an off-mains, battery powered miniature detection unit capable of performing a proprietary assay technology on specific target nucleotide sequences in accordance with CDC guidelines, including control sequences for appropriate test result interpretation. Included in the kit will be all supporting equipment associated with the manipulation of the sample and the reagent materials. Potentially, this kit could be self-contained in a rugged suitcase-like enclosure designed for transportation and use in urgent, remote and rural locations. Although the system is designed for simplicity, pipetting skills and understanding of sterile technique will be required by the operator. This is a field deployable system which detects pathogen viral RNA specific to the COVID-19 virus within 45 minutes from sample collection. Each individual system is expected to be capable of processing up to 40 specimens per 24hr period.

In addition to the lab system, reagents and consumable /single use disposable materials will be provided separately as individually pouched kits capable of supporting two assays. The kits will be packaged as multiples in cartons designed for transportation an use in field deployed scenarios.

We are highly dedicated to doing all that we can to support the immediate needs of potential COVID-19 patients and the containment strategies associated.

Best wishes and keep safe,

Liam

Liam Kelly
President and C.E.O.

P: +1.610.225.6808 | M: **(b)(6)**
E: liam.kelly@teleflex com

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550 E. Swedesford Road, Suite 400, Wayne, PA 19087

Teleflex.com

From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

Dear Mr. Forlenza,

Thank you very much for your letter. I appreciated having the opportunity to hear from you on today's call. I am copying my Chief of Staff, Keagan Lenihan, who will follow up with you.

Steve

From: Vincent Forlenza <vincent_forlenza@bd.com>
Date: March 17, 2020 at 4:05:06 PM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

Vincent A. Forlenza
Executive Chairman

BD
1 Becton Drive, Franklin Lakes, NJ 07417 USA MC: 097
Office: 201-847-7306 Fax: 201-847-5361
Email: Vincent.Forlenza@bd.com Website: www.BD.com

From: Roy Smythe [rsmythe@somalogic.com]
Sent: 3/30/2020 12:26:55 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: FW: Outreach from Roy Smythe and SomaLogic
Attachments: COVID-19 SomaScan Response - Platform Use Exemplars - March 2020.pptx

Steve,
Resending as I know you are absolutely swamped.
We are getting good initial traction with pharma, but to accommodate some of the direct health system and medical school work any direction to some sources of support would be welcomed. Some important patient samples are not being sourced through pharma due to timing issues, etc.
I am pulling as hard for you as I can, personally.
Best,
Roy

From: Roy Smythe <rsmythe@somalogic.com>
Date: Thursday, March 26, 2020 at 11:33 AM
To: "Stephen.Hahn@fda.hhs.gov" <Stephen.Hahn@fda.hhs.gov>
Cc: Mark Messenbaugh <mmessenbaugh@somalogic.com>, Larry Gold <lgold@somalogic.com>, Melody Harris <mharris@somalogic.com>
Subject: Outreach from Roy Smythe and SomaLogic

Steve,

First, thank you for your selfless service at this time. Having an individual like you in your position is a personal comfort to me in the midst of this crisis, and I have shared that sentiment with many.

I will keep this short. We at www.somalogic.com have the world's most sophisticated platform to measure the largest number of proteins in the human body (serum, plasma, urine, other) in the world (5X more proteins than any other enterprise) reproducibly at scale and with clinical speed, and we have been at it for 20 years (>200 peer reviewed pubs, >300,000 assay runs). A large number of pharma entities use us as their primary protein clinical trial patient characterization, drug evaluation and drug development tool. We have also actually partnered with the FDA on gene therapeutic protein product characterization efforts in the past.

We are uniquely valuable in the context of COVID-19 – using protein pattern recognition to help characterize patients (who will get severe disease, who will go on to pulm failure, etc), predict whether or not new or repurposed drugs will work or be toxic, identifying new targets for novel compounds, and seeking patterns that predict quickly whether or not a vaccine will work. Novartis, Regeneron and others are sending us patient samples now, and we are aggressively reaching to everyone else – both pharma and individual investigators.

The outreach is generating a lot of interest, but **I am looking specifically for some temporary funding support from any source (government, foundation, etc.) to offset the cost of running these samples so we don't have to turn anyone down that cannot afford to do so (especially academic investigators and small pharma enterprises).** We are a moderate-sized company, but we are private and cannot afford to run these gratis, or run the risk of being out of business when the next pandemic occurs.

I have attached a deck – please focus only on slides 1-5 (use cases for COVID-19), but feel free to forward.

If you can point me to anyone to help with the funding issue, I would be appreciative. In this context and in the context of the next pandemic, I would legitimately consider us a national strategic asset.

Good luck, Steve, and thank you.

Roy

Roy Smythe, M.D.
Chief Executive Officer | SomaLogic
2995 Wilderness Place | Boulder, CO 80301
Ph: 720.417.7542
rsmythe@somalogic.com
https://somalogic.com

SomaLogic

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/30/2020 12:49:47 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Sterigenics Sterilization Capacity urgently needed

Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 30, 2020 at 12:40:18 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Sterigenics Sterilization Capacity urgently needed

I believe Sterigenics is sueing Cobb country. Erika just got off the phone with Bob, ASPR is looking to see if the current ramp up of ventilators can be sterilized by the existing facilities and their capacity. If not, HHS potentially joins their suit. Think a lot is still up in the air, but sounds like they are moving away from DPA idea. Will update you when there is more.

Sent from my iPhone

On Mar 30, 2020, at 12:19 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Is there any update?

From: Kelly, Liam <liam.kelly@teleflex.com>
Date: March 26, 2020 at 8:38:55 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Sterigenics Sterilization Capacity urgently needed

Dear Dr Hahn,

Thank you for your continued efforts on behalf of patients as we continue to combat COVID-19.

I will be brief, the response from Cobb County has been very disappointing. They are only allowing for a limited reopening of the Sterigenics facility and for the sterilization of PPE only. We need sterilization capacity for critical Medical Devices and we need it immediately.

I respectfully ask you and your team to revisit the discussion with Cobb County. I attach the response from Sterigenics for your reference.

Thanks again for your help,

Liam

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From: Liam Kelly <liam.kelly@teleflex.com>
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Best wishes and keep safe,
Liam

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P: +1.610.225.6808 | M: (b)(6)
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From: "Hahn, Stephen" <sh1@fda.hhs.gov>
Date: Tuesday, March 17, 2020 at 4:29 PM
To: Vincent Forlenza <vincent_forlenza@bd.com>
Cc: Tom Polen <tom_polen@bd.com>, Scott Whitaker <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, "Shuren, Jeff" <Jeff.Shuren@fda.hhs.gov>, "Patel, Chaitali" <chaitali.patel@fda.hhs.gov>, Liam Kelly <liam.kelly@teleflex.com>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: From the Office of Vince Forlenza, BD

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Steve

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Date: March 17, 2020 at 4:05:06 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Tom Polen <tom_polen@bd.com>, Whitaker, Scott <SWhitaker@AdvaMed.org>, Elizabeth Woody <elizabeth_woody@bd.com>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>, liam.kelly@teleflex.com <liam.kelly@teleflex.com>
Subject: From the Office of Vince Forlenza, BD

<image001.png>

Vincent A. Forlenza
Executive Chairman

BD
1 Becton Drive, Franklin Lakes, NJ 07417 USA MC: 097
Office: 201-847-7306 Fax: 201-847-5361
Email: Vincent.Forlenza@bd.com Website: www.BD.com

<Sterigenics response March 25 2020.pdf>

From: Joshua Serchen [jserchen@acponline.org]
Sent: 3/30/2020 5:37:57 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: ACP Letter on Hydroxychloroquine Shortage
Attachments: letter_on_covid19_drug_shortages_2020.pdf

Commissioner Hahn,

Please find attached a letter from the American College of Physicians regarding the COVID-19 induced hydroxychloroquine shortage.

Best,

Josh Serchen

Josh Serchen
Senior Analyst, Health Policy
Governmental Affairs and Public Policy
American College of Physicians
25 Massachusetts Ave, NW Suite 700
Washington, DC 20001
p: 202-261-4518
f: 202-835-0443
e: jserchen@acponline.org

From: (b)(4) (b)(6)
Sent: 3/30/2020 5:37:58 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fw: Briefing Documents to FDA
Attachments: 1.6.2 Meeting Background Materials - Type B PreIND 27Mar2020.pdf; 005544-form-fda-1571-27mar2020_BriefingDoc_.pdf; PLX-COV-01 synopsis_signed.pdf; PLX-COV-02.pdf; PS005544_Cover Letter_27Mar2020.pdf

Dear Dr. Hahn,
This is the Placental mesenchymal stem cell transplantation protocol that we discussed earlier.
Pluristem has already started a compassionate protocol in Israel with good outcome in the first two patients.
See attached e-mail. they have already communicated with your office.

Thank you for everything.
Best,
(b)(4) (b)(6)

From: Yaky Yanay <yaky@Pluristem.com>
Sent: Monday, March 30, 2020 5:01 PM
To: (b)(4) (b)(6)
Cc: Racheli Ofir <racheli@Pluristem.com>
Subject: RE: Briefing Documents to FDA

Dear Chandan,

See attached briefing document we have submitted to the FDA last Friday asking for a pIND meeting for using PLX-PAD in treating COVID-19 severe respiratory complications.
We have started to treat patients under compassionate program in Israel and so far it looks promising. I know time is an essence here, and we are doing everything we can to launch it ASAP.

Thank you and best regards,
Yaky

Pluristem Therapeutics Inc.

Yaky Yanay | **CEO & President**
Matam Park, Building 05, Haifa, 3508409, Israel
T: +972-74-710-7107 | M: +972-54-464-2036
E: yaky@Pluristem.com | W: www.pluristem.com

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 3/31/2020 9:16:31 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Please send to me
Attachments: CTAP-handout-1col-draft3.pdf; CTAP_print_combined_v5_3.30.20.pdf

Here are the documents – the team is working on making the font larger for the graphics document, I'll check on the status of that.

The bullets page is fine to share, but Janet had concerns about sharing the graphics document outside of the White House Task Force; she said she would probably need written permission from the companies since it's possible to guess which products are being referred to. I'll let her know the graphics document has been requested from the Secretary though and I'll get her thoughts on what we need to do – we may need to make the information in it less specific.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 9:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Please send to me

The 3 pager CTAP document
Page 1 the bullet points about the program
Pages 2-3 graphics of pipeline

The Secretary wants this and it may get disseminated - so we need to make sure there is not CCI present. When can you get this to me?
Thanks
Steve

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 3/31/2020 12:05:39 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: Please send to me
Attachments: UPDATED_CTAP_print_combined_V8_3.30.20.pdf; CTAP-handout-1col-draft3.pdf

If it's not too late, here's an updated version of the graphic with the wording tweaked on the front page for the "Actions to Accelerate" for Hyperimmune Globulin, so the font could be increased. I've re-attached the bullets page as well.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Guram, Jeet
Sent: Tuesday, March 31, 2020 11:14 AM
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Here is the latest version of the graphic, and I've re-attached the bullets page as well.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 11:05 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Ok thx

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 31, 2020 at 10:29:25 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Got it, she had permission for it to go to the White House Task Force so sharing it with the Secretary should be perfectly fine. I'll send the version of the graphic with the larger font size as soon as it comes in, which should be later this morning.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 10:25 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Don't disagree but would like to share with the Secretary and deliver the appropriate caveats

---

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 31, 2020 at 9:50:15 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Guram, Jeet
Sent: Tuesday, March 31, 2020 9:17 AM
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: Please send to me

Here are the documents – the team is working on making the font larger for the graphics document, I'll check on the status of that.

The bullets page is fine to share, but Janet had concerns about sharing the graphics document outside of the White House Task Force; she said she would probably need written permission from the companies since it's possible to guess which products are being referred to. I'll let her know the graphics document has been requested from the Secretary though and I'll get her thoughts on what we need to do – we may need to make the information in it less specific.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 9:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Please send to me

The 3 pager CTAP document
Page 1 the bullet points about the program
Pages 2-3 graphics of pipeline

The Secretary wants this and it may get disseminated - so we need to make sure there is not CCI present. When can you get this to me?
Thanks
Steve

From: Taylor, David [taylor.ds@pg.com]
Sent: 3/31/2020 8:07:16 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Taylor, David [taylor.ds@pg.com]; Vinson, Todd [vinson.t@pg.com]
Subject: P&G Collaboration

Business Use

March 31, 2020

Dr. Hahn,

It was a pleasure to meet you at the White House yesterday. As I shared during the briefing, P&G is committed to helping address the outbreak of coronavirus (COVID-19) and will continue to serve the public with our health and hygiene products during this challenging time. Also, we are actively evaluating options as to how to repurpose our technical and intellectual property assets to help assist the government response to this pandemic. I appreciate your offer of assistance; below are efforts we already have in-process where we could use FDA's assistance:

Emergency Ventilators
P&G is partnering with a non-profit start-up, **Venti-Now**, to design and produce emergency ventilators that meet FDA requirements. The emergency ventilator will fill an important need to get oxygen enriched air to patients in the early stages of ARDS. This frees up scarce full featured ventilators. The Venti-Now unit has been tested and reviewed at the University of Cincinnati Medical Hospital. It has a simple design using in-stock components to quickly scale to thousands. The ventilator bags are disposable and thus prevent cross-contamination. The units can be easily carried with one hand and used in regular and portable hospital settings. Venti-Now has addressed feedback from the FDA on the initial design and has passed all the requirements in the testing at UC Medical. The next step is to generate the data required for FDA approval over the next 2-3 days. We expect to have the submission ready by Friday, Monday latest. Venti-Now will request FDA approval next week and will immediately begin production and licensing of the units to help support the need of the 6 to 23 million Americans who will need ventilators during this pandemic. The cost is expected to be in the range of (b)(4) ***We request help to accelerate FDA approval once the submission is received***.

(b)(4)

(b)(4)

In addition to these aforementioned examples, we hope to have further viable options to assist the government's response to this pandemic soon. Thank you for your partnership. If you have any questions on any of these initiatives, please have your team contact Todd Vinson **(b)(6)** at vinson.t@pg.com

Thanks,
David

David S. Taylor
Chairman of the Board, President and CEO
Procter & Gamble

From: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Sent: 3/31/2020 8:12:50 PM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]; Daniel O'Day [daniel.oday@gilead.com]; (b)(6) Joseph.J.Grogan@who.eop.gov; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; Anand Shah (Anand.Shah@fda.hhs.gov) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Tisha Guzman [Tisha.Guzman@gilead.com]

Subject: EXTERNAL Telecon: Therapeutics Check-In
Attachments: 04-01_RDV_Strategic_Update_vFF[1].pdf
Location: 1-888-204-1150,, (b)(6)

Start: 4/1/2020 12:30:00 PM
End: 4/1/2020 1:30:00 PM
Show Time As: Busy

Required Attendees: Daniel O'Day; (b)(6) Joseph.J.Grogan@who.eop.gov; Redfield, Robert R (CDC); Woodcock, Janet; Lenihan, Keagan; McGuffee, Tyler Ann A. EOP/OVP; Shah, Anand

From: A FPR (b)(6)
Sent: 3/31/2020 8:53:12 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: New and Novel MNA Liquid Medicine for COVID-19 safely cures COVID-19; Why is Media Ignoring It? (2/5)

Hello,

Tara Chand, the innovator of the new and novel MNA liquid medicine, shares that the media is suppressing good news on a quick on a fast-acting solution to the COVID-19 epidemic. Tara Chand is the Founder & CEO of a boutique innovation enterprise active across seven market verticals, including human health (IPG. Inc.).

Chand describes his novel COVID-19 liquid medicine innovation, "First, the MNA liquid medicine had been innovated to be inhaled via a nebulizer to fumigate the respiratory system, including the entirety of the lungs, to physically destroy and kill all COVID-19 viruses hiding deep in the lungs, in the millions of alveoli therein.

Next, the MNA liquid medicine when packaged as an aerosol, would fumigate the exterior of a potential host/carrier of COVID-19, to physically kill and destroy all COVID-19 bacteria in the immediate vicinity of a patient, and his/her personal belongings, rendering them free of the COVID-19 virus.

The MNA liquid medicine contains the most powerful destroyer of all viruses on contact, and is derived from natural sources, is inherently safe to cleanse a person of COVID-19, both inside and outside, and any type of SARS virus.

Tara Chand is the innovator of the new novel liquid medicine that destroys COVID-19. He is available for media interviews.

Media Contact: Spencer Clark, Internet Promise Group, clark@internetpromisegroup.com (310) 787-1400

Thank you!

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 4/1/2020 8:56:31 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: FDA 2019-nCOV SITREP - 31 March 2020

No problem

Stephanie is going to print bc she is at HHS w you this morning

---

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: April 1, 2020 at 8:12:46 AM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: FDA 2019-nCOV SITREP - 31 March 2020

Also want this printed. Thanks
Steve

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: March 31, 2020 at 8:10:52 PM EDT
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Sigg, Jim <Jim.Sigg@fda.hhs.gov>, Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>, Carter, Lionel <Lionel.Carter@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>, Tse, Tania <Tania.Tse@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Mayne, Susan <Susan.Mayne@fda.hhs.gov>, Musser, Steven M <Steven.Musser@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>, Solberg, Tim <Tim.Solberg@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Tyler, James <James.Tyler@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Malais, Tanya <Tanya.Malais@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Measer, Gregory <Gregory.Measer@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Rubinstein, Wendy <Wendy.Rubinstein@fda.hhs.gov>, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>, Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Boon, Caitlin

<Caitlin.Boon@fda.hhs.gov>
Subject: FDA 2019-nCOV SITREP - 31 March 2020

FDA Response to COVID-19
SITREP #52 ; 31 March 2020

FDA U.S. FOOD & DRUG ADMINISTRATION

DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals ,and Communications

- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target 04/01

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

- Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)
- Request from the Embassy of Pakistan to be included in the list of countries covered by the EUAs for remdesivir and Abbott's diagnostic test is being considered by CDER.

Medical Product Development & Availability

DIAGNOSTICS

- Pre-EUAs: **261 [+12]**
- LDTs: **117 [+5]** LDT firms have indicated that they have completed validation and will initiate testing[1]
- EUAs:
- Submissions: **100 [+12]**
- Amendments: **12 [+2]** requests, **6 (+1)** have been granted; **2** required re-issue of the original EUA
- Issued: **23** (**22** molecular; **1 [+1]** blanket EUA for molecular tests**; 0** serological)
- Manufacturer Test **Notifications**[2]**: 37 [+3]** firms have notified us, **33 [+3]** serology and **4** PCR.

PPE: CDRH is evaluating 24 non-NIOSH-approved respirator EUA requests for KN95s that indicate they have the European CE mark or the Australian Register of Therapeutic Goods Certificate of Inclusion.

VENTILATORS: CDRH authorized the addition **4** ventilator products to Appendix B of the ventilator EUA

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

HUMAN DRUGS: 32 [+6] pre-INDs, **13 [+5]** INDs, **0** Pre-EUAs, **3 [+1]** EUA requests[3]; **1** EUA issued (chloroquine/hydroxychloroquine)

- Remdesivir: **589 [+15]** EIND requests authorized to date; ACTT trial - **274 (+21)** patients enrolled (440 target) at 37 sites

(b)(4)

- Convalescent Plasma: CBER has granted—and continues to grant—numerous EINDs for convalescent plasma

Inspections

- **ORA Inspections**:
- ORA sent **20** requests for records to firms pursuant to authority under 704(a)(4) of the FD&C Act. **17** firms confirmed receipt of the request. To date, **1** site sent all records requested & **7** others submitted partial records.
- OEIO and DSS has increased our surveillance of products manufactured or shipped from firms whose inspections have been postponed.
- **CBER**: FDA/CBER continues to work to ensure cGMP compliance by seeking potential solutions when inspections and FDASIA 706 authority are not possible.

- **CDER:** Applications for albuterol MDI and lopinavir/ritonavir (a President's Emergency Plan for AIDS Relief (PEPFAR) tentative approval resubmission) have been prioritized. An assessment of manufacturing for an albuterol MDI was acceptable. An API facility for lopinavir/ritonavir recently received a warning letter **(b)(5)**

Medical Product Supply Chain[4]

OUTREACH TO PRODUCT MANUFACTURERS			
Product	**# Contacted**	**# Responded**	**Assessment as of 03/25**
Biologics	58	52 (89%)	No negatively impacted firms, no supply chain disruptions
Human Drugs	183	170 (93%)	No major supply chain disruptions (One respondents has reported a drug shortage associated with the COVID-19 outbreak. Drug product is not medically necessary. Other oral beta-blockers can be used as alternatives.) All the pending chloroquine, hydroxychloroquine, and azithromycin ANDAs have been requested for prioritization. Albuterol MDI will be added to this list soon.
N95s	23	12 (52%)	9 firms report being adversely affected. Common concerns include insufficient raw materials, backorders, export restrictions, workforce shortages, and government nationalization of their facilities.
Surgical Masks	42	28 (67%)	14 firms report being adversely affected. Common concerns include insufficient raw materials, the manufacturer has shut down production of non-N95 masks, export is banned, and shortages of workers and raw materials.
Surgical Gowns	59	33 (65%)	14 firms report being adversely affected. Manufactures indicated they are working at lower capacity because of workforce shortages, raw material shortages, travel bans, and export issues.
Surgical Isolation Gowns	16	7 (44%)	5 firms report being adversely affected. Common concerns were that the company had closed, export restrictions, employee shortages, raw material shortages, and government restrictions.
Gloves	294	104 (35%)	12 adversely affected. Common concerns included lack of raw materials and workforce shortages. Manufactures also noted they are experiencing an increase in demand.
Surgical accessories and non-surgical isolation gowns	232	84 (36%)	25 adversely affected
Infrared Thermometers	26	20 (77%)	15 adversely affected. Overarching concerns reduction in workforce and supply shortages of critical components (e.g., sensor).
Ventilators	102	21 (21%)	3 adversely affected. Main reason given was supply chain disruptions originating in China.
Vent support devices	62	5 (8%)	2 adversely affected. Main reason given was supply chain disruptions originating in China.
Essential Devices - INTL[5]	340	**240 [+3] (71%)**	24 adversely affected. Manufacturing issues that include but not limited to workforce availability, transportation delays, and longer lead times with suppliers.
Animal Drugs	94	**87 [+1] (93%)**	7 adversely affected

Fraudulent Products

- Warning Letters: **13 (+1)** issued; **44** pending
- 1 issued today to Neuro XPF for a CBD product.

Food Safety

- **CFSAN released two guidance documents:**
- FDA Provides Flexibility Regarding Labeling Requirements for Menus During the COVID-19 Pandemic
- Guidance for Industry: Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency

Legislative Activities

- **Briefings/Hearings Today:** N/A
- **Upcoming Briefings/Hearings:**
- 4/2, 2:00PM: FEMA Region III Bicameral Hill member and staff briefing; FDA briefer is TBD.
- 4/3, 2:00PM: Bicameral Hill member and staff briefing; FDA will be available for Q&A; Dr. Shah will represent FDA.

Communications

- **Released today:**
- Press statements – FDA Continues to Accelerate Development of Novel Therapies for COVID-19
- Web updates:
  - CTP: FDA Submits Request to Court to Extend Premarket Application Deadline for Certain Deemed Products
  - CDER: Coronavirus Treatment Acceleration Program (CTAP)
  - CFSAN is now linking from agency FAQ page to a *For Consumers* drop down on the CFSAN COVID-19 FAQ page
    - Added *What's New* section on CFSAN COVID-19 FAQ page to highlight new info.
  - CVM: CVM landing page for COVID-19
  - CVM: Industry FAQs: Animal Food Safety and the Coronavirus Disease 2019 (COVID-19)

Operations

- PHS Deployments: **150 (-19)** officers are deployed; **82 (+25)** officers are rostered to deploy

Requests for Information (RFIs)[6]

- Total Received: **141 (+16)**
- Total Pending: **24 [17%]**
- Total Resolved: **117 (+14) [83%]**

External Situation Reports

- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 30, 2020
- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 31, 2020

[1] EUA submissions should be submitted within 15 working days of FDA notification
[2] Resulting from the new Regulatory relief policy update
[3] 1 EUA request is for a product already available under IND
[4] *Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.*
[5] China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain
[6] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/31/2020

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/1/2020 1:55:58 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Fwd: Materials: WHTF 04.01.2020
Attachments: COVID-19 Vitals_31 March 2020.docx; 2020.04.01 WHTF.docx; 2020.04.01 FDA COVID Related News.docx; Serology Plan.docx

Print serology plan for me?

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Date: April 1, 2020 at 1:48:25 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Materials: WHTF 04.01.2020

Good Afternoon Dr. Hahn,

Attached are the 4 documents for today's WHTF meeting:

1. COVID-Vitals 03.31.2020 document
2. Detailed rundown of center activities
3. Media document of press on COVID-19
4. Serology Plan

Thank you,
Jakea

Jakea Copeland
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Desk Phone: (301) 796-7050
Email: Jakea.Copeland@fda.hhs.gov

From: Rachel Noble (b)(6)
Sent: 4/1/2020 5:04:07 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Expand COVID-19 Testing

Rachel Noble
(b)(6)

April 1, 2020

Dear Stephen M. Hahn,

Dear President Trump:

I am writing as a member of our nation's laboratory medicine team, which includes pathologists and laboratory professionals, to raise my concerns about America's capacity to meet patient testing needs for COVID-19. To date, other countries are doing a better job addressing the diagnostic needs of their patients.

In order to get ahead of this virus and implement the appropriate measures, we need to be mass testing people rather than just at their sickest before they even qualify for testing, especially since their condition can so rapidly deteriorate at that point and can have already infected others prior, and by the time they get tested or get their test results back, they may only have a few days left to live. The CDC says that an estimated twenty-five percent of people with Coronavirus may be completely asymptomatic. A subsequent article stated that between 25 and 50 percent may be asymptomatic and feel great, not even knowing they could be carrying and passing along the virus, yet still positive for COVID-19. If we are going to do all that we can to get the economy moving while also safeguarding everyone, I'm inclined to think we need an overabundance of testing available to have the capacity to test those who are not only severely and critically symptomatic. Since healthcare workers need special PPE for COVID-19 patients beyond the standard precautions in order to safeguard themselves and other patients, why not have testing more readily accessible, if not standard protocol before receiving healthcare and perhaps before entrance into any public gatherings such as possibly even Easter services you were hoping for, provided there is room to offer them while keeping everyone at least 6 feet apart?

With regards to someone who tests positive, would it be possible to have them on a type of "house arrest" (with some kind of tracking device used in "house arrests") where they are unable to leave a designated area for however long it takes, with someone sent to them after 14 days to give them another test for clearance? I don't know the legal ramifications of these things or if they are feasible, but I'm hoping that these ideas will at least help brainstorm to help get a better control on this virus.

Additionally, I plead with you to use your presidential power to mandate that companies step up to make the items to stay ahead of the virus accessible to the public in abundance, which are currently constantly sold out everywhere and not offered online, which increases the needs for people to make repeated trips to multiple grocery stores all over the place, and thus increases the amount of time spent in public places around other people rather than self-isolating at home. Namely, these items essential in tackling the virus amonf the general public include: masks, Lysol spray, Lysol wipes, hand sanitizer, and thermometers. Other items that are frequently unavailable but needed, and thus increase the number of times people need to expose themselves to multiple public places in their search, include but are not limited to toilet paper. These items need to be made available online as well to limit exposure/the need to be around others. However, regulations should be put in place with regards to how often and how many of these items can be sent to any particular address so that hoarding does not take place. Personally, I live in Pennsylvania and work in NJ, and with as quickly as the virus is spreading in NJ, I find I deeply concerning that items to protect against the spread of the virus haven't been available in any Walmart, CVS, Walgreens, Wegmans, Whole Foods, Giant, Shop Rite, Rite Aid, Target, McCaffrey's, Big Lots, or any other place I can think of either in my town or other stores within 45 minutes of me in either NJ or PA since the time of our first cases in the country despite dozens of trips to these stores each week. If these items are unable to be produced and provided in the overabundance that we should have at times like these, perhaps it would even be worth considering having manufacturers ship these limited items to The White House, and then designate staff at the White House ship them out according to limits for each physical address? Again, perhaps that's not realistic, but it may be something still worth considering to help you come up with a better solution to these needs and complications. I also don't mean to imply that there would be no need for grocery stores but when people are unable to obtain the most basic and particular essentials needed to protect themselves it cause anxiety and despair; whereas, in actually, there should be an overabundance of these items everywhere, at every entrance to every store and in every check out lane, to encourage those who may not be taking the virus seriously enough.

Our government needs to take assertive action to expand the capacity of our nation's clinical laboratories to provide diagnostic testing for the COVID-19 virus in order to hasten its containment. The

United States' clinical laboratories are having difficulties securing the resources needed for COVID-19 testing. Labs need an unfettered supply of test kits, instrumentation, reagents and DNA extraction kits, as well as the virus samples necessary to accurately and reliably identify this virus. In addition, clinical labs and their vendors need enhanced regulatory flexibility to meet these needs. Commercial vendors, who have test materials to detect COVID-19, are restricted from providing guidance on the use of these products, i.e., test methods, because the tests are not FDA cleared. This restriction, which is acceptable at most times, delays the implementation of critically needed assays in times of crisis. We request that vendors are temporarily released from these restrictions and are allowed to provide guidance for testing for the COVID-19, which will facilitate the implementation and more wide-spread use of these tests.

I urge you to direct the federal government to take immediate action to help our nation's laboratories expand laboratory testing capacity needs as quickly as possible.

As a laboratory professional dedicated to providing quality patient care, I stand ready to assist you in our nation's time of need.

Thank you!

Sincerely,

Sincerely,
Rachel Noble

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/2/2020 4:41:02 PM
To: Bill de Blasio [(b)(6)]
Subject: Re: FDA Letter

Received, Mayor de Blasio
Our teams are working on the application.
Best
Steve Hahn

From: Bill de Blasio < (b)(6) >
Date: April 2, 2020 at 12:25:19 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: FDA Letter

Commissioner, please confirm that you received this. Thanks, Bill

Sent from my BlackBerry 10 smartphone.

From: Bill de Blasio
Sent: Wednesday, April 1, 2020 9:55 PM
To: SH1@FDA.HHS.GOV
Subject: Fw: FDA Letter (Clean)

Commissioner, really appreciate your responsiveness. Mitch Katz will get you the medical data you need. Let me know if there are any questions or concerns. I can be reached anytime at (b)(6) Thanks, Bill

Sent from my BlackBerry 10 smartphone.

From: Kayla Arslanian < (b)(6) >
Sent: Wednesday, April 1, 2020 9:50 PM
To: Bill Deblasio
Subject: FDA Letter (Clean)

Dr. Stephen M. Hahn, M.D.
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

April 1, 2020

Dr. Hahn,

I write to you regarding New York City's urgent need for ventilators to manage the current and, more importantly, the coming influx of patients with COVID-19.

Specifically, I request that you approve the Emergency Use Authorization (EUA) application for the automatic resuscitator called the Spiro Wave. This device would provide a critical emergency alternative to ICU ventilators. We are asking for extraordinarily expedited action because of the unprecedented times we are living through.

New York City continues to be disproportionately impacted by this global pandemic, with over 45,000 positive cases of COVID-19 and over 1,000 deaths to date. While we appreciate the resources that the federal government has made available thus far, our need continues to quickly outpace our resources and the City faces constant shortfalls of critical supplies. Right now, we need 400 ventilators by April 5th and another 2,500 to 3,000 to make it through next week.

Approval of an EUA would allow the Spiro Wave to be quickly distributed throughout New York City and the nation, and help build desperately needed capacity during this crisis. Completed units will be coming off the line as early as Friday, meaning that approval this week will save lives. This would not only augment our current resources but would also allow medical professionals to treat more patients in the coming weeks, which are projected to be increasingly challenging.

Further, the Spiro Wave was designed by a consortium of leading experts to operate a manual resuscitator safely and reliably. The design has been evolving in response to clinical feedback until as recently as this past weekend. Moreover, the device has also been reviewed by our public hospital clinicians and they have requested to use it as soon as possible.

The need for available material and personnel increases by the day as COVID-19 spreads throughout the country. The World Health Organization (WHO) and the Centers for Disease Control (CDC) estimates indicate that in the next 30 days, there will be a national shortage of ventilators in the range of 150,000 to 300,000 units.

I urge you to expedite the EUA for the Spiro Wave automatic resuscitator so that New York City and cities across the country can access this life saving resource. The decisions we make now will result in lives saved.

Sincerely,

Bill de Blasio

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/6/2020 11:12:36 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: POTUS CEO Call talkers
Attachments: Pharma CEO Call 04062020.docx

Do these work for you?

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 4/6/2020 12:00:55 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: CEO Talkers

(b)(5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 1:56:52 PM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Journal publisher raises red flags about French malaria drug study

Absolutely
S

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Date: April 6, 2020 at 1:33:04 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fw: Journal publisher raises red flags about French malaria drug study

FYI. I think that the issue of patient selection is one that is going to come up over and over again, as per our conversation this morning.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Monday, April 6, 2020 1:31 PM
To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Subject: Journal publisher raises red flags about French malaria drug study

Journal publisher raises red flags about French malaria drug study
By Sarah Owermohle
04/06/2020 01:30 PM EDT
The society that recently published a French study that suggested malaria drug hydroxychloroquine could help coronavirus patients has raised formal concerns about the research.
In a statement, the International Society of Antimicrobial Chemotherapy says it "shares the concerns" raised by critics of the study, which was published on March 20 in a society-run journal. Such statements of concern are often the first step towards retracting a scientific paper.
The small study, led by controversial French researcher Didier Raoult, helped fuel growing interest in the drugs in the United States. President Donald Trump has cited Raoult's work while championing hydroxychloroquine as having “very, very encouraging” early results against the coronavirus.
But the society, which runs the International Journal of Antimicrobial Agents, has now said that the French study does not meet their standards — citing its "lack of better explanations" for how study participants were chosen. Experts have pointed out that Raoult's team chose who would get the drug versus who would not, even though the gold standard for clinical trials is to assign patients to treatment groups randomly.
Raoult has not yet responded to a request for comment on the society's statement.
The results from other studies of hydroxychloroquine have been mixed, and the studies themselves have been small.
The president's focus on hydroxychloroquine has sparked divides within his administration, where several health officials feel there has been outsized attention on the drug even as other medicines are in trials.
The Food and Drug Administration last week authorized emergency use of the drug for severely ill patients but acknowledged there was still limited data about whether the treatment is effective.
To view online:

https://subscriber.politicopro.com/health-care/whiteboard/2020/04/journal-publisher-raises-red-flags-about-french-malaria-drug-study-3978980

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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 2:24:37 PM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: Re: Talking Points for 12:30pm call

Thanks, Jeet. Well done

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: April 6, 2020 at 12:22:44 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Talking Points for 12:30pm call

Dr. Hahn, please see below and attached the talking points for opening today's call. Dr. Shuren will take the lead in answering questions from industry.

Talking points for AdvaMed Call

(b)(5)

- I'm joined this morning by Dr. Jeff Shuren, Director of the Center for Devices and Radiological Health, who will help in answering your questions.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, April 6, 2020 10:08 AM
To: Hahn, Stephen; Shah, Anand; Guram, Jeet; Shuren, Jeff; Stenzel, Timothy; O'Leary, Brendan; Gitterman, Steven; Lenihan, Keagan; Rom, Colin; Cristinzio, Dayle; Lynch, Sarah; Caliguiri, Laura
Subject: EXTERNAL Telecon: CEOs (COVID serology tests)
When: Monday, April 6, 2020 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 1-877-348-6535,,, **(b)(6)**

US Dial-In Number: (877) 348-6535
Conference ID: **(b)(6)**

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 7:12:05 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Subject: Fwd: Dr Rosy Joseph outcomes data
Attachments: Covid19book2.xlsx; ATT00001.htm

For our point of contact. I've asked them to hold additional data until that PoC Is identified.
Thanks
Steve

From: Zelenko Family (b)(6)
Date: April 6, 2020 at 10:13:32 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Dr Rosy Joseph outcomes data

Please see the outcome data of my colleague. She is a Columbia med graduate with 40 years experience in internal medicine and nephrology. She is at Hackensack hospital. Extremely well respected

Sent from my iPhone

Begin forwarded message:

From: "R. Joseph" (b)(6)
Date: April 6, 2020 at 8:54:52 PM EDT
To: Zelenko Family (b)(6)
Subject: my latest data with names removed

Rosy E. Joseph, M.D.

(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 8:41:38 AM
To: Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]
Subject: Fwd: Zelenko Updates - important / Please show to the President
Attachments: Lettre au preésident pour extension ATU -JCG-OK.pdf; A reasoned COVID strategy adapted to the here and now JC GHALEB - EN.pdf

---

From: Zelenko Family (b)(6)
Date: April 7, 2020 at 8:41:01 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Mark Meadows (b)(6)
(b)(6)
Subject: Zelenko Updates - important / Please show to the President

Thanks, please provide any further guidance on what I can do. I am attempting to generate as much data as fast as possible.

FYI -

1- The government if Brazil has adopted my protocol and is advising all doctors to initiate treatment immediately in the outpatient setting and not to go to the hospitals which are overwhelmed. Ambassador Ernesto Araujo (Foreign minister of Brazil) has reach out to me and I will be talking to them today.

2- I have been fighting with Israel's minister of health (Prof. Litzman) for 2 weeks. Yesterday Israel approved the use of the hcq, and Dr. Alon Moses, Israel's leading ID doctor (Hadassah hospital), has started a clinical trial already using the protocol.

3- One day after I gave an interview to their biggest media outlet, Italy began using hcq on a broad scale this week, lets keep an eye on their mortality figures.

4- I am leading a pilot project to prophylax the city of dnipropetrosk, Ukraine (3.2 million people in metro and surrounding areas). If successful, it may be scaled country wide.

5- The government of Peru reached out to me yesterday. I hope to connect today.

6- I have been contacted by officials from Moscow and had a conference with the country's leading doctors. Im not sure what they have decided.

7- Leading doctors in France have petitioned the French president 2 days ago to adopt my protocols. Not sure of the impact.

Dear Doctor Zelenko,

I am writing on behalf of Ambassador Ernesto Araújo, Foreign Minister of Brazil.

We would very much like to establish contact between you and Brazil´s team of doctors who are on the forefront of the coronavirus treatment, for the purpose of sharing findinds and other relevant information. Doctors in Brazil have administered hydroxicloroquin to over 60 thousand patients.

Please let me know if you would be interested in this and what channel of communication would be most convenient. I understand how busy you must be at this time. Feel free to reach me via whatsapp on the number listed here.

Best regards,

Flavio Sapha
Advisor to the Minister
Ministry of Foreign Affairs of Brazil

(b)(6)

Information from France

Dr. Jerome Corsi / Dr. Zelenko - national podcast

https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fyoutu.be%2FZ7SDemHGl8U&data=02%7C01%7C%7Cccf4839c1c764955c70008d7dae82eaa%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637218563051737584&sdata=TwSM4OffZVfIrP8LZPZuq0eWaPSHuHiQzhjVy12AbjY%3D&reserved=0

Mayor Giuliani / Dr. Zelenko - Podcast

https://www.youtube.com/watch?v=1TJdjhd XG8

Recent Reuters article

https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmobile.reuters.com%2Farticle%2Famp%2FidUSKBN21O2VO&data=02%7C01%7C%7Cb4504a2c3c3f4118593308d7daef5376%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637218593733416902&sdata=8JiwFOg9E6LCkYY32MwoMI1BtCq7ARj3Zh%2Fshvm3NRo%3D&reserved=0

On-line physician petition / rational for treatment

https://docs.google.com/document/d/1ka76CL50hR_a0b5oIhEAVY4gfyqkJcBxXBcP0r2nrz0/edit?fbclid=IwAR0ss1p0lsPhLkSFhO6_8vJK19BUispAREVcn0oi09iajG-Pq4HDCMFTQdg

Israel approval of use hcq

https://www.ynet.co.il/articles/0,7340,L-5696160,00.html

Ukraine proposal

Dr Zelenko,

This is the original idea that we sent Rabbi Kaminetzki in Ukraine.

Please understand it was a proposal and obviously we did not make any commitment to them regarding you and your time. All we said is that we will endeavor to have a call with Dr Zelenko. Of course if a longer term relationship is envisioned, compensation should certainly be part of it. Just wanted to get that out of the way!

This is going to hit Ukraine.
To save Ukraine's elderly, it is urgent that a task force be formed to utilize private resources to deploy Dr. Zelenko's drug regimen.

The needs are as follows:
• Test kits
• Personal protection for front line medical personal
• Zelenko drug regimen

Re the Drug regimen
Dr Zelenko will remotely oversee the drug program; meaning he will make a video in Russian/Ukrainian explaining his methods so Ukrainian doctors can follow and Zelenko is to be availble for consultations.

Community of Dnipro will be responsible to distribute drugs, PPE and test kits to the local hospital and clinics.

A register of elderly high risk patients will be created that will be monitored and overseen by a team of doctors overseen by Zelenko.
Data will have to be updated daily so that Zelenko and his team can do virtual rounds...
A procurement team needs to be setup and endowed with resources to acquire the neccessary drugs and equiment

If you think the above is possible you would need to get the following:
Buy-in from Ukrainian govt
Manage the distribution

Once this program to save the elderly of Ukraine is anounced, it is likely other oligarchs will line up to contribute.

There are 7.4 million people ages 65+
Zelenko guestimates that his drug regimen costs $20 per person. Say together with increase in drug price and PPE it's $30 per person. That's a total of $222 million. Private contributions should be sources for half of the amount I.E. 111 million and the government matches them.

Being that not everybody becomes infected and not all infected are in need of hospital. This can end up benefiting the entire Ukraine....but for marketing purposes we focus only the elderly .

Best, Mendel

PS I am thinking big. Though I must say It's possible that group in Dnipro will want to limit this to just the Jewish population they serve.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 8:42:15 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Fwd: Zelenko Updates - important / Please show to the President
Attachments: Lettre au preésident pour extension ATU -JCG-OK.pdf; A reasoned COVID strategy adapted to the here and now JC GHALEB - EN.pdf

When our point of contact is identified, please let Dr. Zelenko know.
thanks
S

From: Zelenko Family (b)(6)
Date: April 7, 2020 at 8:41:01 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Mark Meadows (b)(6)
(b)(6)
(b)(6)
Subject: Zelenko Updates - important / Please show to the President

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Ministry of Foreign Affairs of Brazil

(b)(6)

Information from France

Dr. Jerome Corsi / Dr. Zelenko - national podcast

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Mayor Giuliani / Dr. Zelenko - Podcast

https://www.youtube.com/watch?v=1TJdjhd XG8

Recent Reuters article

https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmobile.reuters.com%2Farticle%2Famp%2FidUSKBN21O2VO&data=02%7C01%7C%7Cb4504a2c3c3f4118593308d7daef5376%7C84df9e7fe9

f640afb435aaaaaaaaaaaa%7C1%7C0%7C637218593733416902&sdata=8JiwFOg9E6LCkYY32MwoMI1BtCq7ARj3Zh%2Fshvm3NRo%3D&reserved=0

On-line physician petition / rational for treatment

https://docs.google.com/document/d/1ka76CL50hR a0b5oIhEAVY4gfyqkJcBxXBcP0r2nrz0/edit?fbclid=IwAR0ss1p0lsPhLkSFhO6 8vJK19BUispAREVcn0oi09iajG-Pq4HDCMFTQdg

Israel approval of use hcq

https://www.ynet.co.il/articles/0,7340,L-5696160,00.html

Ukraine proposal

Dr Zelenko,

This is the original idea that we sent Rabbi Kaminetzki in Ukraine.

Please understand it was a proposal and obviously we did not make any commitment to them regarding you and your time. All we said is that we will endeavor to have a call with Dr Zelenko. Of course if a longer term relationship is envisioned, compensation should certainly be part of it. Just wanted to get that out of the way!

This is going to hit Ukraine.
To save Ukraine's elderly, it is urgent that a task force be formed to utilize private resources to deploy Dr. Zelenko's drug regimen.

The needs are as follows:
• Test kits
• Personal protection for front line medical personal
• Zelenko drug regimen

Re the Drug regimen
Dr Zelenko will remotely oversee the drug program; meaning he will make a video in Russian/Ukrainian explaining his methods so Ukrainian doctors can follow and Zelenko is to be availble for consultations.

Community of Dnipro will be responsible to distribute drugs, PPE and test kits to the local hospital and clinics.

A register of elderly high risk patients will be created that will be monitored and overseen by a team of doctors overseen by Zelenko.
Data will have to be updated daily so that Zelenko and his team can do virtual rounds...

A procurement team needs to be setup and endowed with resources to acquire the neccessary drugs and equiment

If you think the above is possible you would need to get the following:
Buy-in from Ukrainian govt
Manage the distribution

Once this program to save the elderly of Ukraine is anounced, it is likely other oligarchs will line up to contribute.

There are 7.4 million people ages 65+
Zelenko guestimates that his drug regimen costs $20 per person. Say together with increase in drug price and PPE it's $30 per person. That's a total of $222 million. Private contributions should be sources for half of the amount I.E. 111 million and the government matches them.

Being that not everybody becomes infected and not all infected are in need of hospital. This can end up benefiting the entire Ukraine....but for marketing purposes we focus only the elderly .

Best, Mendel

PS I am thinking big. Though I must say It's possible that group in Dnipro will want to limit this to just the Jewish population they serve.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/7/2020 6:21:44 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenil
Subject: RE: FOR REVIEW: **(b)(3) 42 USC 247d-6b(d), (b)(5)**

Thx

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: April 7, 2020 at 6:20:33 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: RE: FOR REVIEW: **(b)(3) 42 USC 247d-6b(d), (b)(5)**

I believe Brooke reached out to the Center on this, will check back.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, April 7, 2020 6:19 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: FOR REVIEW: **(b)(3) 42 USC 247d-6b(d), (b)(5)**

See the HQ item below. Is Mary Beth aware?

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Date: April 7, 2020 at 11:48:17 AM EDT
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>, Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>, Strom, John (OS) <John.Strom@hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Ethier, Kathleen A (CDC) <kbe0@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>, DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>, Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>, Meredith.L.Austin@usbordencg.mil <Meredith.L.Austin@usbordencg.mil>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Blatner@hhs.gov <Blatner@hhs.gov>, Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>, DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: FOR REVIEW **(b)(3) 42 USC 247d-6b(d), (b)(5)**

Dear Disaster Leadership Group Members and Colleagues:

Thank you for your participation in COVID-19 Disaster Leadership Group (DLG) Meetings. We are soliciting feedback to

(b)(5)

(b)(3) 42 USC 247d-6b(d) , (b)(5)

Suspense Date: Please offer any edits to the (b)(3) 42 USC 247d-6b(d) , (b)(5) paper to DLGDESK@HHS.gov **by 5:00 PM on Wednesday April 8, 2020**.

2. **FOR INFORMATION**: Please find the attached "**International MCM Sharing Policy Framework**" document, which is an existing policy framework for any requests to use HHS-held MCMs internationally.

We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message. Please address any questions related to this request to the DLGDESK Resource Mailbox at DLGDESK@hhs.gov.

Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) 245-0719
Daniel.Dodgen@HHS.Gov | **www.phe.gov**

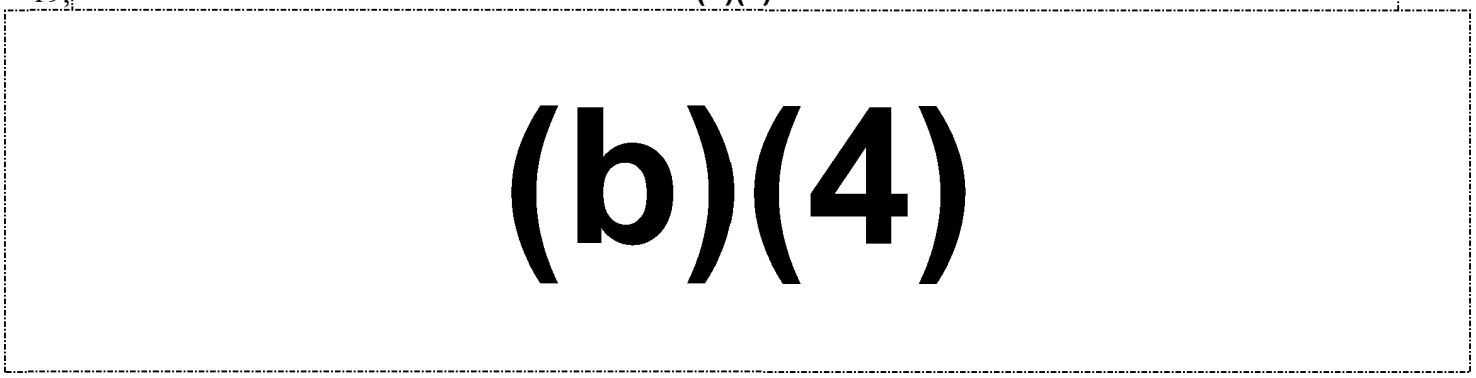
From: Tim Crew [tim.crew@lannett.com]
Sent: 4/9/2020 7:30:14 PM
To: Birx, Deborah L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2e45952d70d4e2d84d839843f3cda9f-HHS-emg5-cd]; Anthony.Fauci@nih.hhs.gov; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
CC: 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]; Azar, Alex (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4db7abd56a7e478883f5cd8e2e8a18d3-HHS-Alex.Az]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Samuel Israel [Samuel.Israel@lannett.com]; Kristie Stephens [kstephens@lannett.com]; Bill Burke [bb@rubicondc.com]
Subject: Urgent Request for COVID 19 Advice to Support the Manufacturing of Contingent Supplies of the Prescription Combination Antiretroviral Medicine Lopinavir/Ritonavir (Generic of AbbVie Brand Kaletra)

Sir / Madam:

I am writing to you as the CEO of Lannett, a publicly traded, USA generic manufacturing business. We presently produce Lopinavir and Ritonavir Oral Solution, the only FDA-approved, lower cost, generic antiretroviral in our Carmel, New York plant. The only other lopinavir/ritonavir combinations currently available are the brand forms (Kaletra).

There are numerous trials globally seeking to determine if this therapy is helpful in addressing the COVID-19 outbreak. We have attached one recently encouraging analysis on the matter. However, we are neither clinicians able to judge efficacy and safety or politicians able to direct priority. We, are however, a nimble USA medicines manufacturer and we need your help now if the Administration wishes to have a material expansion of a contingent supply of this product from us over a near term horizon.

We typically produce only around **(b)(4)** bottles annually for the product's core HIV indication. Each bottle provides about 16 doses. That relatively small quantity supplies the vast majority of demand for the solution, and that dosage form can potentially provide enhanced swallow-ability for certain compromised patients. The branded solid oral product volume is several times higher by equivalent doses. Since the outbreak of COVID 19, **(b)(4)**



Again, we do not assume to know or predict the success of this particular therapy. Regardless, we stand ready to make far more than we have already. However, for us to be able to produce significant additional contingent supply in a **(b)(4)** we need Administration guidance, prioritization and support right now. If we wait until all necessary proof of efficacy is available, many weeks will have been lost from the potential production schedule.

Please know we have also reached out to other FDA offices to request their assistance in these matters, so that those patients diagnosed with COVID-19 might have access to this potentially lifesaving medication if their physicians recommend it.

We are available at any time to further discuss the matter.

Regards,

Tim Crew

CEO Lannett

https://www.sciencedaily.com/releases/2020/04/200406120130.htm

From: Mark (b)(6)
Sent: 4/9/2020 8:11:26 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: The Drug Leronlimab

Mr. Hahn,

CytoDyn has a drug Leronlimab that has positive results on people in the treatment of Covid-19 patients. The UK has requested it. Why can't this drug be approved expeditously?

Hydoxychloroqiune has cardiac complications and that may rule me and others out from taking it.

Thank you for all you do.

Time is of essence.

Mark Terry

From: James Minow [james.minow@curejm.org]
Sent: 4/13/2020 12:43:36 PM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Hydroxychloroquine Shortage
Attachments: Cure JM Letter to FDA Hydroxychloroquine.docx

Dear Commission Hahn,

Attached please find a letter from the Cure JM Foundation regarding our position on the potential and actual shortages of hydroxychloroquine (Plaquenil), often prescribed for children suffering from juvenile myositis, a rare and debilitating autoimmune disease. Thank you for your thoughtful consideration.

James Minow
Executive Director
Cure JM Foundation
(b)(6)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 4/15/2020 9:32:26 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Talkers for David Liam
Attachments: david lim talking points.docx

Of course

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:24 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Talkers for David Liam

Can you send the previous version?
Thanks much.
S

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: April 15, 2020 at 9:23:11 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Talkers for David Liam

Yes! Working on it now re: testing accuracy and our conversation. Will get Jeff/CDRH buy in and send your way. Thank you!

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, April 15, 2020 9:20 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Talkers for David Liam

Hi Stephanie,
Thanks for the call and I appreciate your willingness to hear my feedback. Some of the talkers, I don't think are completely accurate.

Could you send them again to Keagan and me/
Thanks for your team's incredible work.
Steve

From: Rita Estep (b)(6)
Sent: 4/15/2020 11:52:06 AM
To: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: URGENT

Dr. Hahn,

in addition to a letter I mailed to you week ago, I would extend to you this e-mail below:

Prominent US molecular biologist, Judy Mikovits, has recently stated that the Wuhan Covid-19 virus, based on it's genomic structure, very unlikely has it's origin in nature, as a matter of fact she stated that it is almost impossible that this virus has a natural origin. She believes strongly that the virus has man made laboratory additions and genetic modifications, and it being a chimeric structure. She also expressed concerns about the biosafety of those level 4 laboratories, not only in China but also in the USA.

Pentagon bluntly denying any possibility that the Covid-19 virus could have been emerged as a product of the biological weapon research in Wuhan, China, - is deeply concerning. What exactly is the state of bio-weapon research in China AND in the United States ? How many laboratories in our country are involved in such research and how is an absolute adequate safety level guaranteed in those laboratories ? Aren't these questions that the general population is entitled to get answers to … ? After all OUR lives and livelihoods are at stake ! Answering these question is not accomplished with a blunt "NO".

We, the public in the USA, and as I believe also our scientists, know very little factual about this virus.

We do not know all about it's origin, though it is a modification of a so called horseshoe bat virus. Virology experiments and studies on those viruses have been done in both US and in China. As we recently found out our NIH sold the study of horseshoe bat virus to the Wuhan virology lab in 2015 after these so called "gain-of-function"studies were ended here, for China to continue carrying on those studies. It has been debated that China paid NIH $ 3.7 Million for this, but also there has been leaks about US supporting monetarily those Chinese studies.

It is likely that this Covid-19 virus is a chimeric laboratory modified virus, - what does it matter now (using the famous words of Mrs. Clinton) whether meant as biological weapon virus or a product of some other virology research, which either accidentally escaped or was for some reason released from the Wuhan laboratory, - since by now the virus has effectively functioned as bio-weapon … with the numbers of people killed and infected worldwide.

It appears likely that the humanity will never red itself from this virus, but that it will permanently stay in the environment. It has now reached also remote Amazonian tribes.

What kind of properties does this coronavirus have? Is it a so called slow virus which never leaves your body, but stays dormant in tissue and then has capability to re-activate when triggered for some reason. There are known cases in patients who already had been deemed to be "recovered". So, the question is, is this a re-activation … or a re-infection? If it is a re-infection then do the body's own natural antibodies help anything ? Or are the antibody levels different in different people ? Or do we have already mutations in that virus so that it is able to re-infect the population ?

The virus has been found in the spinal fluid of the so called "recovered" people. This would support the fact that the virus indeed is a slow virus, and persists in the body for lifetime. HIV virus is one example of this. So, if this is the case, do the people maybe have to take a medication (after it is first developed) for lifetime ?

What symptoms can the infected person then expect to have for a the rest of his/her life ? Is the person going to be to some degree immuno-incompetent ? Like AIDS patients … - we do know that Covid-19 has HIV insertion in it's genomic structure. The main symptom of this virus is pneumonia and respiratory distress, if one is moderately to severely ill. The worst case is full blown ARDS, which then can leave the patient respiratory compromised for life. But this virus also has central nervous system tropism, it was likely developed as such. Those long term symptoms are still to be found out.

How does this virus spread ? Studies show that it can been spread up to 26 feet in air by coughing. Some people keep repeating that one has to be in close contact for longer than 10 minutes … which really does not make much sense, medically seen. This virus is deemed to be very infectious and therefore the amount of viral load one is exposed to is not going to be significant to make a difference, is it , for one to become infected ? Also, how infectious is the virus to general population, what is the infectiosity quotient ? it is now estimated that one person can infect in average 5.7 other people. It has been found - besides in saliva and sputum, also in stool and sewage water. It has been tested from blood. Is it also possible to get this virus via sexual contact, like HIV ? It has been found in air as aerosolized product, and according to this finding patients of course should be placed in hospitals in negative air pressure rooms. Already in January Philippines reported that this was done for a Covid-19 patient there. Yet we have not heard about this in our country. The reason of course is that we not have enough such rooms, be barely have enough other equipment, like PPE, to protect hospital workers.

What is the mortality of this virus ? it is not clear yet. Different countries have different statistics. One really cannot assess this unless way more testing has been done.

How long does the virus stay vital in in animated objects ? Some studies state up to 9 days in certain materials ... but for sure several hours and often up to 72 hours.

How can the virus been killed in our surroundings ? High percentage alcohol can do this ? and bleach … but not vinegar …

Is this virus going to be "seasonal"? it does not quite appear so, since it is spreading at the same time to both of the hemispheres of the globe.

Why are some people getting very sick while others only are either slightly symptomatic or completely asymptomatic, yet carriers ? Does this have something to do our genomic make-up? There are reports that our blood groups would make a difference, that type A would be more vulnerable but type O protective. And reports that females would be less vulnerable to get this illness as severe as males would. Why do some people become so sick that they get multi-organ failure ? This is said to be result of our own immune response to the virus, so called "Cytokine storm".

We need to have capability to test as many symptomatic people as possible, and even those who are not having any symptoms but likely were exposed and therefore may be asymptomatic carriers. With generalized wide spread testing we could easily practice meaningful and effective quarantine. It would not be impossible to develop a home testing kit comparable to a home pregnancy test.

I am also wondering about the numbers about Covid-19 cases released here in the US, as on 04.15.20, stating that from about 600,000 infected 26,000 are deceased and … 30,000 RECOVERED. – What are the rest 540,000 doing ? are they possibly running around infecting others ?

The attempt to determine if someone has developed antibodies … and to be deemed as "safe" to go back to work, is one way to try to confront this epidemic, but is the detection of antibodies a true guarantee for them to be safe from re-infection, - we do not know for sure, do we ? And does a detectable level of antibodies secure that this person no longer is infectious ? Or should we always do the viral PCR as well ? and is even this a secure assessment ?

How about the possible therapies, - or at least means to alleviate the illness in those who get and have gotten infected, or even use the means to prevent someone to get infected. Is this even possible, or will the end situation be such that every single person will ultimately get infected, that being only matter of time? We are counting on a heard immunity to protect other people, but would this work ?

We do have medications which have proved to make a difference in the course of illness, even a difference between the ultimate outcome, life and death. Hydroxychloroquine is one of those medications. This is an old medication form 1950s, and has been used for rheumatoid arthritis and lupus for decades. It is relatively safe medication, retinopathy known as long term side effect after months and months of continuous usage, which is not needed to treat covid-19 virus; many protocols state patients improved or completely recovered after only 24 hours to 5-6 days of treatment with Hydroxychloroquine. Our government has made it impossible any longer for a physician to prescribe this medication for Covid-19 as off-label usage. If one tries to call it in to a pharmacy provider is asked for positive Covid-19 test result for that patient. Yet that same patient who went to see his PCP was not allowed to get this test done for symptoms consistent with Covid-19. Either the test was not available or that PCP was ignorant about the symptoms … or deemed those symptoms to be too mild for a testing at that time. That very same patient then had to be brought to ER with an ambulance only 4 days later. This example is only one of many. We by now have over 22,000 deaths in the US, that number only 3 weeks ago having been just over 220 … so the increase has been 100 fold in only 3 weeks. What are we waiting for ? Should we not apply the medications we have to safe lives ?!

If the 'studies' will result with a conclusion that Hydroxychloroquine is undeniably effective as I believe it is - and safe, as it is, - then who all will have "the blood on their hands" of those who died ? Those will be you all, in CDC, FDA, NIH, HHS …. The first question coming then in mind is, - who all had financial profitable connections with pharmaceutical industries wanting to deny this while being in heat and hurry developing their own alternatives … - whether medications or vaccines … which were and will not be available in time to save those already dead and still dying.

Remdesivir is another medications used in the past for Ebola. This medication has way more significant side-effects than Hydroxycholoroquine. Or are we waiting for the vaccine to be available, in 12- 18 months ? What is the death toll going to be then ? And has the virus by then mutated so that we need to develop yet another vaccine for it to be effective?

After all this information is known to one, is it not a wonder that one has lost all confidence in so called Covid-19 "experts", as well as the governmental agencies like NIH, HHS, CDC, FDA … and also WHO; beyond that our technocrats and industrialists and governmental representatives have acted with their own monetary benefits overriding the faith of the nation and it's citizens while trying to advance their global government agenda. Based on their decisions we were completely unprepared for any pandemic of this magnitude and supply chains for essential medical equipment were not available in this country, not manufacture here neither stored here, and lack of essential medications for other ailments came evident as well due to the manufacturing of those being shifted to Asia. This has been as criminal as one only can say about the way how China has been acting about the Covid-19 crises.

After this all is over we not only have to deal with the medical disaster but also with economical and humanitarian disaster caused by the Covid-19 pandemic to the entire world. We must hold the entities and people responsible for this epidemic to become the pandemic of the century criminally liable.

China of course has veto in the International Court as well as in the United Nations. It can only be "get" by all nations cancelling their international loans to China. Manufacturing has to be brought back from China to the original countries. China can not allowed to steal our intellectual properties by any means, whether by them sending so called "students" to our educational institutions or us accepting employees from China in our industry that is vulnerable to espionage. Our telecommunication within the information and communication technology and our internet vulnerability has to be protected.

Our President has been accused of hypocrisy and cover-up, in his expressions about China and WHO. The left-linked media say that Trump is trying to cover up his mistakes by blaming WHO. This is simply not true, so here we are clearly dealing with the fake news. As far as what comes to China, anyone with an average intelligence understands - which the White House press conference reporters obviously do not possess, - or more likely are deliberately confronting the President with fake news questions - that USA is bound to stay in "good relations" with president Xi and the Chinese government … as long as we are importing essential products from China, essential to our technology, health and other industry. So there you have it, as simple as it can be said. It could be said publicly … if it wouldn't show our present state of weakness too obviously.

Any biological weapon research has to be limited and controlled or completely abolished by international laws.

Also, - CDC's Robert Redfield recently expressing publically following sentiment … ' we have to continue working with WHO now and cannot stop doing so amidst the Covid-19 pandemic' … is to say the least, insulting to the general public.

Beyond all this said above we also have to deal now with a previously unimaginable and totally unprecedented situation of expanding poverty and hunger in this country, due sky rocketing unemployment and lack of work force in agriculture, and lack of our infrastructure flexibility to get products to market where they now would be needed, after the change of the consumer base in the country due Covid-19 due the state wide closure of many private and governmental businesses. Our economical livelihood is severely impacted, and this may be not so easy to reverse. People are standing in row of cars waiting help from food banks, a scene never before imaginable in the United States of America. People are going to die from hunger and other direct result of lack of food, care and needed medical services for other medical concerns besides Covid-19. At the same time farmers are dumping millions of gallons of milk to ground due to lack of a possibility getting it transported to various sites of need, which now has drastically changed. Also, agricultural seasonal labor is crucially needed.

Families are losing their loved ones in ICUs where they cannot be visited and these patient are dying alone. Dead bodies are buried in mass graves with a plaque of name on the pine caskets, only to be re-covered later for a proper burial ?

Sincerely,

Dr. Estep

From: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]
Sent: 4/20/2020 8:14:18 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: FW: Materials Inquiry: Telecon Interview: The Justice and Drew Show
Attachments: TALKING POINTS FOR Monday 4.20.20.docx

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Sunday, April 19, 2020 9:08 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Materials Inquiry: Telecon Interview: The Justice and Drew Show

Updated attached! New content highlighted.

Stephanie Caccomo
Press Officer

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

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Sunday, April 19, 2020 8:56 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: Materials Inquiry: Telecon Interview: The Justice and Drew Show

Holding.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Sunday, April 19, 2020 8:41 PM
To: Block, Molly <Molly.Block@fda.hhs.gov>; Copeland, Jakea <Jakea .Copeland@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Materials Inquiry: Telecon Interview: The Justice and Drew Show

Please hold one second—updated version with talkers from today's news stories coming shortly!

Stephanie Caccomo
Press Officer

Office of Media Affairs
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U.S. Food and Drug Administration
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Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Sunday, April 19, 2020 8:12 PM
To: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Materials Inquiry: Telecon Interview: The Justice and Drew Show

See attached (ignore the document name).

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Sunday, April 19, 2020 7:18 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Materials Inquiry: Telecon Interview: The Justice and Drew Show

Also, please include any materials for "Commissioner Prep: VP Videocon with Governors" scheduled for 8:30am tomorrow.

Thanks in advance!
Jakea

From: Copeland, Jakea
Sent: Sunday, April 19, 2020 7:16 PM
To: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov) <Laura.Caliguiri@fda.hhs.gov>; Molly Block (Molly.Block@fda.hhs.gov) <Molly.Block@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Frank Olivarria (Frank.Olivarria@fda.hhs.gov) <Frank.Olivarria@fda.hhs.gov>
Subject: Materials Inquiry: Telecon Interview: The Justice and Drew Show

Good Evening!

Are there materials for "The Justice and Drew Show" interview, scheduled for 8:20am tomorrow? If so and not already sent, please send as soon as possible.

Thanks,
Jakea

-----Original Appointment-----
From: Sheehy, Janice **On Behalf Of** Hahn, Stephen
Sent: Friday, April 17, 2020 1:38 PM
To: Hahn, Stephen; Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Molly Block (Molly.Block@fda.hhs.gov); Caccomo, Stephanie
Subject: Telecon Interview: The Justice and Drew Show
When: Monday, April 20, 2020 8:20 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where (b)(6) (hotline) (b)(6) (backup)

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 4/20/2020 8:28:06 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: RE: Document for WH **(b)(5)**
Attachments: **(b)(5)**

Thanks Dr. Hahn – I've added responses below, but just let me know if you have other thoughts. Also I'm looping in others so everyone has the latest draft of the handout.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, April 20, 2020 7:52 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: Document for WH **(b)(5)**

Jeet,
This looks good. A couple of comments/suggestions

(b)(5)

(b)(5)

Thanks
Steve

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: April 19, 2020 at 6:26:28 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Document for WH (b)(5)

Dr. Hahn, please see attached a draft handout for your White House briefing tomorrow (the same document is attached in both Word and PDF format). Just let us know if you have any feedback or questions.

(b)(5)

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/20/2020 10:03:28 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Fwd: Blunt/Alexander Doc
Attachments: AlexanderBlunt Doc 4.19 FINAL.docx

Can you give the first review of this and get back to Colin?
thanks
S

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: April 19, 2020 at 3:15:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Blunt/Alexander Doc

Attached is doc requested by Sens. Alexander and Blunt providing an update on potential therapies, tech, monitoring practices, and devices. Let me know what you all think

Thanks!

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 4/27/2020 7:21:47 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: updated talkers for today
Attachments: TPs FOR Monday 4.27.20.docx

Reflects latest serology test (8 total). As well as an FYI on Fauci remarks from yesterday

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/27/2020 7:45:41 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Fwd: Direct Biologics ExoFlo Briefing Document
Attachments: 2020.04.19.CTAP.EXOFLO.BRIEFING DOCUMENT v6.pdf

FYI

From: Mark Adams <mark@adamsatx.com>
Date: April 25, 2020 at 5:35:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Direct Biologics ExoFlo Briefing Document

Dear Dr. Haun,

Congressman Michael McCaul relayed to me your request to see our Briefing Document on our product ExoFlo. I have attached it to this email.

For background, I am the Co-Founder and CEO of Direct Biologics. For the last few years we have been innovating and advancing the science of exosomes that are derived from bone marrow MSC's. This resulted in the creation of our flagship product ExoFlo. We have filed over 2 dozen patents around several very unique aspects of our technology that are unequaled anywhere in the world. Our MSC's are derived from an FDA certified donor and we manufacture and process all of our products to full cGMP standards.

As you will read in our attached briefing, Dr. Sengupta conducted an independent study, under an approved IRB, treating 27 late-stage COVID-19 patients. Of these COVID-19 infected patients, 21 were hypoxic and on oxygen and were 12-24 hours away from being placed on a ventilator with moderate to severe ARDS. Under normal conditions, every one of these patients would have already been intubated and placed on a ventilator. Of these 21 patients, 15 recovered very quickly after treatment with ExoFlo and were discharged within a few days of treatment. Of the 6 remaining patients, 4 have fully medically recovered, yet are elderly and will be discharged as soon as they can get placed into a discharge facility.

Of the 3 ventilated patients we treated, all of them showed initial stabilization and improvement. Today one has been extubated and the other two are fully stable and improving.

ExoFlo begins to reverse the cytokine storm within about 6 hours following treatment, and we believe ExoFlo will also significantly help regenerate the damaged pulmonary cells and lung tissue post-ventelation.

Direct Biologics is filing an Expanded Assess IND on Monday. We are anxious to help more COVID-19 patients with ExoFlo who might otherwise suffer and die on ventilators!

Respectfully yours,

Mark Adams
Chief Executive Officer
Direct Biologics, LLC
512-809-1900
mark@directbiologics.com

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/28/2020 7:21:14 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: For your review: tweets on today's trip

Excellent and approved

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: April 28, 2020 at 7:19:09 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: For your review: tweets on today's trip

Sir, proposed tweets about today—please confirm if this accurately captures your trip.

Joined @VP @Mike_Pence and others in Minnesota today @mayocliniclabs to see first-hand their ongoing investigative efforts on serology diagnostic testing for #COVID19 under the National Expanded Access Treatment Protocol.

. @US_FDA is supporting a national Expanded Access Program to collect and provide convalescent plasma to patients in need across the country. Plasma from recovered COVID-19 patients contains antibodies that may help fight the disease.

From: Moshe (b)(6)
Sent: 4/29/2020 3:00:57 AM
To: Vladimir Zelenko [(b)(6)
(b)(6)
(b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah];
(b)(6)
Subject: Latest Dr. Zelenko Protocol Advice
Attachments: Zelenko-clinical dx protocol.pdf

To All Concerned:
Prime Minister Benjamin Netanyahu; Israel Health Ministry; Mr. Mark Meadows, Chief of Staff - White House; FDA

Dr. V. Zelenko has updated his protocol for the treatment of Covid-19. The information is attached along with a Video put out by the team and a short interview.

G-d has placed you on the forefront of healing your country and the entire world. Implementing this protocol as the standard treatment for Covid-19 immediately will save lives. The statistics speak for themselves, 99.8% of patients that came to Dr. Zelenko's are feeling better. If your waiting for a treatment that is 100%, we are not G-d, that may never exist and none of us have the time to wait. Please forward this information to every hospital and doctor in the country, allowing them to treat patients early. Please give them access to the medicine and permission to treat Covid-19 in the out-patient setting.

The Doctor is available to help in anyway possible. Call him anytime 1-845-238-4214.

Thank you,
Rabbi Moshe Steinerman
Jerusalem, Israel
On behalf of Dr. V. Zelenko

Please see attachment PDF of Protocols

Dr Zelenko

Dr Zelenko

Короновирус. COVID-19. Пандемия 2020

An Important Interview

Doctor: Treat Early With Hydroxychloroquine

[redacted]

[redacted]

Doctor: Treat Early With Hydroxychloroquine

Is hydroxychloroquine a safe and effective treatment for COVID-19 or not? Will Witt gets Dr. Vladimir Zelenko's ...

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/29/2020 8:24:31 AM
To: Daniel O'Day [daniel.oday@gilead.com]
Subject: Re: Our statement

As part of the U.S. Food and Drug Administration's commitment to expediting the development and availability of potential COVID-19 treatments, the agency has been engaged in sustained and ongoing discussions with Gilead Sciences regarding making remdesivir available to patients as quickly as possible.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: April 29, 2020 at 8:24:15 AM EDT
To: Daniel O'Day <daniel.oday@gilead.com>
Subject: Our statement

Dan,
This is our part of the NIAID statement. Look forward to seeing you soon.
Steve

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 4/29/2020 10:30:50 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: UPDATED talkers for morning calls with reporters
Attachments: TPs FOR Thursday 4.30.20 final.docx

Hi Dr. Hahn-
Updated talkers for tomorrow's call with reporters. Happy to call you a bit ahead of the first call with Anna Edney. Thank you!!

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/30/2020 6:55:41 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Re: For review: Quote in NASA Ventilator PR

Approved.
thanks
Steve

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: April 29, 2020 at 10:19:22 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: For review: Quote in NASA Ventilator PR

Hi Dr. Hahn—very cool PR to flag for you. And quote for review.

We are authorizing a ventilator that NASA has made/manufactured. FDA and NASA will each issue press releases. We'll put your quote in the NASA press release as well. Let us know if AM if ok! Thanks!

Quote:

(b)(5)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 4/30/2020 7:32:46 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]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: Re: Too many drug trials could hinder search for coronavirus treatments

Got it. Thanks!

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: April 30, 2020 at 7:21:40 PM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Fwd: Too many drug trials could hinder search for coronavirus treatments

(b)(5)

From: POLITICO Pro <politicoemail@politicopro.com>
Date: April 30, 2020 at 7:20:36 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Too many drug trials could hinder search for coronavirus treatments

Too many drug trials could hinder search for coronavirus treatments

By Zachary Brennan

04/30/2020 07:16 PM EDT

Scientists and drug companies searching for a coronavirus treatment have launched so many clinical trials that some now fear they will run out of patients to enroll, trial sites or personnel to carry out the tests.

There are more than 70 coronavirus drug and vaccine trials now registered with the Food and Drug Administration. Many, but not all, are taking place in the U.S. Although the number of new coronavirus

infections nationwide is still climbing, the frenetic pace at which trials are launching — and the number that are potentially redundant or don't involve enough patients to reach accurate conclusions — could prevent some of these studies from producing useful results.

The lack of federal and state coordination could ultimately hinder efforts to find treatments for the virus. The FDA, which has acknowledged those risks, is pushing drug developers to design studies that compare multiple treatments so they can be tested more quickly and uniformly. But the agency does not have the power to coordinate trials — only to approve their design based on safety and efficacy criteria.

"There are so many trials that we may compete to the point that no trial meets enrollment targets and all are rendered uninformative," said Vinay Prasad, assistant professor of Medicine at Oregon Health and Science University School of Medicine.

A top Food and Drug Administration official sounded a similar warning last week during a webinar run by the Clinical Trials Transformation Initiative (CTTI), which was established by the FDA and Duke University. "We may not run out of patients, unfortunately, but we may run out of research personnel and time," said Janet Woodcock, director of the agency's Center Drug Evaluation and Research.

In China, where stringent infection-control measures sharply reduced the number of new coronavirus cases, two trials of Gilead's experimental antiviral drug remdesivir were halted recently for lack of participants.

Similar problems hampered the hunt for promising Ebola treatments five years ago, during the historic West Africa epidemic. The National Institutes of Health was forced to scuttle a trial of a promising therapy, known as ZMapp, after the outbreak's decline made it impossible to find enough trial participants. It wasn't until 2019 — during another Ebola outbreak — that a trial revealed ZMapp was ineffective.

Trial designers carefully calculate how many patients must be recruited to ensure that results will be statistically significant. The most rigorous trials also involve a control group: participants who do not receive the drug or vaccine being tested, to allow comparisons with participants who do. Carrying out these studies during a pandemic requires frontline medical workers to collect detailed data at regular intervals, adding to their workload at a time when many hospitals are stretched thin.

The "old-fashioned approach of going one investigator at a time doesn't work during a pandemic," said Pamela Tenaerts, executive director of CTTI. Shortages of personnel and facilities ready to carry out Covid-19 clinical trials are already evident, she added.

One issue is that medical centers that are already conducting trials while treating large numbers of severely ill coronavirus patients often don't have the capacity to launch new studies, said Jonathan Zung, executive vice president of clinical trials service provider WCG.

He did not think there was yet a shortage of trial sites or personnel, but he pointed to a related problem — finding enough patients to participate in the studies is proving difficult in some cities. Parts of the Midwest haven't seen enough coronavirus cases to enable trials, he said, noting that the situation is different in hot spots like New York City and New Jersey.

The use of master protocols, which can allow one study to investigate multiple drugs simultaneously, is one possible solution to the clinical trial bonanza. That could reduce the odds of wasting effort through redundant trials, while analyzing enough patients to get a clear signal of whether a drug or vaccine works.

The approach has typically been used to expedite late-stage development of cancer drugs. One recent National Cancer Institute trial enrolled more than 1,800 lung-cancer patients across 650 U.S. medical centers and tested drugs from 10 different pharmaceutical companies.

"The master protocol can be focused around the disease by testing different drugs with a common control group or by testing drugs against each other," Woodcock said. "The most promising drugs move on for further definitive testing."

FDA is encouraging researchers to use the approach because the sizable number of potential Covid-19 therapies is making it harder to quickly set up the trials needed to determine which of the treatments are the most promising. And some of the trials now underway duplicate existing work but may not produce useful data.

For instance, multiple universities are running large, phase 3 trials to determine if the malaria drug hydroxychloroquine is effective against the coronavirus. It's not clear if all those groups will finish their trials if one shows success or failure.

And many trials going on now don't include a control group or placebo, which makes it difficult to tease out the effect of the drug from the behavior of the disease. Prasad said that master protocols could solve that problem by including a placebo group that is blinded, which means that patients and staff are unaware of who received which treatment.

But even if the use of master protocols increases going forward, the lack of coordination among those running the coronavirus trials will make the already difficult task of finding effective treatments even harder, he said.

To view online:
https://subscriber.politicopro.com/health-care/article/2020/04/too-many-drug-trials-could-hinder-search-for-coronavirus-treatments-1928869

From: Zelenko Family (b)(6)
Sent: 4/30/2020 11:08:34 PM
To: (b)(6)
(b)(6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Martin Scholz (b)(6)
Subject: Fwd: WCBS-TV NEWS EXCLUSIVE REPORT ON Dr. Zelenko and Hydroxychloroquine
Attachments: clip_image001.png; ATT00001.htm; S. Korea Study of Prophylaxis.pdf; ATT00002.htm; Brazil 2020.04.15 journal manuscript final.pdf; ATT00003.htm

Sent from my iPhone

Begin forwarded message:

From: Alexander Roberts <aroberts@robertsgeo.com>
Date: April 30, 2020 at 10:17:11 PM EDT
Subject: WCBS-TV NEWS EXCLUSIVE REPORT ON Dr. Zelenko and Hydroxychloroquine

Dear Friends:

Some of you have been following my efforts to allow doctors, **if they choose**, to prescribe Dr. Vladimir Zelenko's treatment of hydroxychloroquine, azithromycin and zinc for early treatment of COVID-19 because of his excellent results in keeping elderly and high risk patients out of the hospital. I have been dismayed at some media reports on the Left and the Right, which have made the drug a political football, conflating the science with President Trump's promotion of the drug ("Take it. What do you have to lose?"). The fact is that hydroxychloroquine is a drug prescribed hundreds of millions of times over 50 years and which the FDA considers safe and effective for Malaria, Lupus and Rheumatoid Arthritis.

Tonight, Carolyn Gusoff of WCBS-TV News did a fair report on Dr. Zelenko and the FDA's approval of a clinical trial at a hospital on Long Island for his three-part therapy:

https://newyork.cbslocal.com/2020/04/30/coronavirus-exclusive-meet-the-doctor-behind-the-hydroxychloroquine-treatment-for-covid-19/

Instead of allowing use of the drug cocktail when Dr. Zelenko and some clinical studies say it is most effective—taken early upon symptoms of COVID-19 by a high risk individual—Governor Cuomo has made it nearly impossible for patients to obtain the drug early by requiring them to enroll in a clinical trial at a hospital after a test that can take several days. Dr. Zelenko feels it is not effective once the disease has time to damage the lungs, and that is consistent

with some of the studies. In addition, he says that the zinc is critical, since it's a proven anti-viral.

While the three-drug cocktail including hydroxychloroquine is still unquestionably an "unproven" treatment, there is **no approved treatment** and as such, should patients with a potentially fatal disease be denied the choice of **something** that may help? According to Dr. Richard Zeckhauser, a professor of economics and decision theory at Harvard's Kennedy School, and Maryaline Catillon, formerly a hospital director in France, waiting for results of Randomized Clinical Trials "is inappropriate" with 1,500 people dying every day…

https://www.hks.harvard.edu/centers/mrcbg/news-events/COVID Zeckhauser

I am perplexed as to why, with so many people dying of COVID-19, Governor Cuomo and his Health Commissioner Howard Zucker have shown no interest in verifying or debunking Dr. Zelenko's claims, even after he released all of his patient data at my request. If it turns out that this well studied drug IS effective taken early in the disease, our leaders will have to answer for the deaths of thousands by preventing doctors from prescribing the drug "off-label," which is frequently allowed for other drugs.

If you are interested, I've attached two **recent clinical studies** on hydroxychloroquine (one in South Korea and another from Brazil) that got no play in the media.

All the best,

Alec

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 5/5/2020 7:04:01 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Quick hits on news today

Morning Sir—just wanted to flag a couple of things prior to your convos this morning. Both stories copied below, providing topline quick summary:

STAT has an article about Gilead's checkered past with drug pricing; notes company line about being thoughtful on distro of remdesivir. Also makes a note that trial results came right before company reported Q1 results

Washington Post: US absent from virtual vaccine summit, senior admin official: *A senior Trump administration official said Monday the United States "welcomes" the efforts of the conference participants. He did not explain why the United States did not join them. "Many of the organizations and programs this pledging conference seeks to support already receive very significant funding and support from the U.S. government and private sector," said the official, who spoke on the condition of anonymity under White House rules for briefing reporters.*

STAT: With remdesivir, Gilead finds itself at strategic crossroads, with its reputation (and far more) at stake

By Nicholas Florko @NicholasFlorko *and* Damian Garde @damiangarde

May 5, 2020

Never in modern times have such high hopes for millions of lives rested on one single company.

As the world struggles to fight off Covid-19, Gilead Sciences has been thrust in the spotlight with remdesivir, the antiviral drug that on Friday the Food and Drug Administration gave emergency authorization to treat coronavirus patients. Doctors are already preparing for a surge of requests from potential patients. Anthony Fauci, the nation's top infectious disease expert, is sounding close to buoyant. The markets are showing signs of recovery. And President Trump, who has vilified the drug industry since before his election, welcomed Gilead CEO Daniel O'Day to the Oval Office.

But the 33-year-old biopharma company has a well-documented history of charging high prices for lifesaving therapies. And its next steps — notably how much it decides to charge for remdesivir — could determine whether Gilead, and even the drug industry itself, is lauded as the hero of the coronavirus pandemic or condemned anew as price gougers.

"At the end of the day, I think this will certainly help the industry's reputation," O'Day, told investors on a conference call last week. "The ability to solve a human crisis like this because of the decades of investments … the general public will see that."

One pharma lobbyist who spoke on the condition of anonymity put it more bluntly: "We've got a perfect opportunity to show our value — and not come across like greedy bastards."

In interviews with STAT, analysts, drug pricing experts, activists, and lobbyists — including those who work with Gilead — underscored the monumental challenge facing the company and O'Day. Gilead is building good will with a promise to donate enough doses to cover roughly 200,000 patients. But after those are used up,

Gilead will have to start charging. Just how much has vast implications for Gilead's business, reputation, and standing in the pharmaceutical industry.

If Gilead prices remdesivir too high, it will invite the scorn of the world, likely reigniting the bipartisan push in Washington for sweeping reforms to America's drug pricing system. If it prices cheaply, the company is unlikely to recoup the roughly $1 billion it expects to spend on developing the drug, disappointing investors and tanking the stock price. Sitting on the fence could leave both sides unsatisfied.

"I think that Daniel O'Day and his ilk would be incredibly ill-advised to test the world's patience on this," said James Krellenstein, co-founder of PrEP4All, an organization that has fought Gilead over the cost of its HIV drugs. "An outreached hand does not mean you can't make it into a fist."

Learn how remdesivir works against the SARS-CoV-2 virus, which causes Covid-19. *Alex Hogan/STAT*

Attention — and scathing attacks — are not new to Gilead. The company brought America a hepatitis C drug that cost $1,000 a pill, found itself in a protracted and messy legal battle with the U.S. government over patents, and priced HIV drugs so high it birthed an international social movement of AIDS activists.

The company's checkered past with pricing has lawmakers, activists, and even sympathetic lobbyists concerned that Gilead will squander its moment in the name of corporate profits. Gilead's pricing scandals, including a backlash in 2013 from pricing its hepatitis C treatment Sovaldi at $84,000, still reverberate within the company.

"If there is one overriding sentiment, it's to avoid another Sovaldi," said a former Gilead executive, who spoke on condition of anonymity to speak candidly about the company's current leadership. Gilead's mistake wasn't the price itself, the executive said, but a failure to clearly explain to the public why Sovaldi was worth the money.

"This is an incredible challenge," the executive added. "At the end of the day, this is a price that Dan O'Day and the board are going to have to live with."

For AIDS activists in particular, Gilead has represented a corporate villain like no other.

Larry Kramer, the legendary playwright and firebrand who founded the activist organization ACT UP in 1987, is now 84. But in an email to STAT, his animus toward the company was hardly tempered.

"Gilead has always been selfish, greedy, tricky pigs," Kramer said. "I have always hated them."

He's not alone. Gilead transformed AIDS from a death sentence to a chronic condition: The company has marketed 11 AIDS drugs since its founding, including the first FDA-approved drug for the prevention of HIV, Truvada. Despite those advances, Gilead has earned the reputation of price gougers from the HIV community, who have protested the company in the streets, in the courtroom, and in Congress.

Among the most vociferous criticism is over a drug called tenofovir, approved in 2001 as the HIV treatment Viread. Over the ensuing years, tenofovir would become the backbone of highly effective — and highly lucrative — combination therapies for HIV, including Atripla, Complera, and Truvada. As revenues for the medicines piled up, Gilead had discovered a novel version of tenofovir, abbreviated TAF, that appeared more potent and less likely to cause bone damage and kidney toxicity.

According to HIV activists, who sued in 2016, Gilead deliberately left TAF on the shelf for several years in order to milk the remaining patent life of the original tenofovir, raising the prices of its medicines all the while. The first TAF-containing HIV regimen was approved in 2015, 14 years after the debut of tenofovir. Gilead has denied the accusation.

Truvada, first approved as a treatment for HIV in 2004, became the center of Gilead's most contentious pricing controversy. In 2010, researchers funded by the Bill and Melinda Gates Foundation determined that Truvada was dramatically effective at preventing uninfected people from contracting HIV. The drug won approval for a pre-exposure prophylaxis, or PrEP, in 2012.

At the time, Gilead's executives repeatedly insisted that PrEP had no commercial future, expressing doubt that HIV prevention would catch on. And then it did. Over the past seven years, the number of patients taking Truvada for PrEP soared into the hundreds of thousands.

But activists say the biggest barrier to getting more patients on PrEP — and preventing untold HIV transmissions — is Gilead's insistence on charging $20,000 a year for the drug. That price, which has steadily risen since 2004, has galvanized a global movement to force Gilead to charge less and give up the patents behind PrEP. Gilead, now in a legal fight with the federal government over Truvada's patents, has committed to donating enough of the drug to supply 200,000 patients each year for up to a decade, but activists see that as more of a stunt than a substantive solution.

"For years they said they didn't view PrEP as a commercial opportunity," said Krellenstein, of PrEP4All. "Fast forward a few years and it's a multibillion-dollar franchise driven by their price-gouging on the drug. We haven't seen any hopeful signs yet."

Gilead has earned the scorn of the hepatitis C community, too.

When the company launched Sovaldi in 2013, public outcries over the drug's price erupted from Delhi and Madrid to San Francisco and Paris.

Protestors haunted Gilead executives everywhere they went, from the J.P. Morgan Healthcare Conference in San Francisco, to the Leerink Conference in New York, and even an AIDS conference in Melbourne.

Activists wore then-Gilead CEO John Martin's face as a mask and plastered it on oversized $1,000 dollar bills. They even organized marches complete with hearses and planes towing anti-Gilead banners.

Each time Gilead has garnered the scorn of activists, lawmakers in Washington have taken notice, too.

In May 2019, Gilead CEO O'Day was dragged before the House Oversight Committee to answer questions about the price of Truvada.

"People are dying for no reason," Rep. Alexandria Ocasio-Cortez (D-N.Y.) told O'Day.

In July 2014, the Senate Finance Committee launched an 18-month investigation into the cost of Sovaldi, exposing, the authors argue, that Gilead's sky high price tag had less to do with how much it spent developing the drug and was more about finding the highest possible price without inviting unmanageable scorn from activists. Gilead has disputed the report's findings.

The 134-page report was laden with evidence supporting that conclusion, from internal Gilead charts graphing potential activist anger, to quotes from Gilead executives urging the company not to "fold to advocacy pressure."

For all of its high-priced medicines and accusations of profiteering, there's an unsettling reality inside Gilead's glassy campus in Foster City, Calif: The company has been getting less and less profitable.

In late 2015, when Gilead's stock price hit an all-time high, the company's franchise of hepatitis C medicines minted about $5 billion every quarter. Today, thanks to price cuts and competition, that figure has been decimated to just $700 million. The company's HIV business remains strong, but Gilead's forays outside of antiviral medicine — most notably a $12 billion acquisition of the cancer drug maker Kite Pharma — have failed to pay off in substantial new revenue.

Investors have grown listless, pressuring the company to buy one or more of its rivals before its position worsens and it falls prey to an unwanted takeover.

Gilead needs a hit.

And then came remdesivir. Last week's news that the drug significantly sped up recovery time for patients with Covid-19 happened to arrive the day before Gilead's conference call to discuss first-quarter earnings. The company has said again and again that it isn't looking at remdesivir as a major business opportunity and doesn't intend to profit from the pandemic. But Wall Street analysts, who speak on behalf of investors the world over, had a consistent response: Why not?

"I'll ask a controversial question," said Geoffrey Porges, a well-regarded analyst from SVB Leerink, on last week's call. "Gilead has generated attractive returns for investors from treating hepatitis C …, from treating HIV and turning it into a chronic disease, and from building a really important global stockpile of antiviral for influenza. So, what's special about Covid?"

Why, Porges continued, shouldn't investors assume Gilead will produce Sovaldi-like profits on remdesivir once the company's donated doses have elapsed?

O'Day, who faced three versions of the same question, was noncommittal.

"We need to be very thoughtful about how we can make sure we provide access to our medicine to patients around the globe and do that in a sustainable way for the company, and for you as shareholders," he said. "We acknowledge that."

Defining "sustainable" seemed to unsettle Wall Street. After the call, two analysts downgraded Gilead's stock over concerns about remdesivir's profitability. Others forecast only modest revenue from the drug, at a margin far below what Gilead investors might come to expect. The next day, Gilead's share price fell 8%.

For many analysts gaming out the economics on remdesivir, there's simply no path to blockbuster sales. Phil Nadeau, a biopharma analyst at Cowen, sees remdesivir topping out at a few hundred million dollars a year in revenue, a figure so small it's almost immaterial to Gilead's profits and losses.

"I think to their credit they probably realize that and think, why would we take any reputational risk over what is, to them, basically pennies?" Nadeau said in an interview.

WaPo: The world came together for a virtual vaccine summit. The U.S. was conspicuously absent.

By
William Booth,
Carolyn Y. Johnson and
Carol Morello
May 4, 2020 at 2:53 p.m. EDT

LONDON — World leaders came together in a virtual summit Monday to pledge billions of dollars to quickly develop vaccines and drugs to fight the coronavirus.

Missing from the roster was the Trump administration, which declined to participate but highlighted from Washington what one official called its "whole-of-America" efforts in the United States and its generosity to global health efforts.

The online conference, led by European Commission President Ursula von der Leyen and a half-dozen countries, was set to raise $8.2 billion from governments, philanthropies and the private sector to fund research and mass-produce drugs, vaccines and testing kits to combat the virus, which has killed more than 250,000 people worldwide.

With the money came soaring rhetoric about international solidarity and a good bit of boasting about each country's efforts and achievements, live and prerecorded, by Germany's Angela Merkel, France's Emmanuel Macron, Britain's Boris Johnson, Japan's Shinzo Abe — alongside Israel's Benjamin Netanyahu and Turkey's Recep Tayyip Erdogan.

"The more we pull together and share our expertise, the faster our scientists will succeed," said Johnson, who was so stricken by the virus that he thought he might never leave the intensive care unit alive last month. "The race to discover the vaccine to defeat this virus is not a competition between countries but the most urgent shared endeavor of our lifetimes."

A senior Trump administration official said Monday the United States "welcomes" the efforts of the conference participants. He did not explain why the United States did not join them.

"Many of the organizations and programs this pledging conference seeks to support already receive very significant funding and support from the U.S. government and private sector," said the official, who spoke on the condition of anonymity under White House rules for briefing reporters.

Public health officials and researchers expressed surprise.

"It's the first time that I can think of where you have had a major international pledging conference for a global crisis of this kind of importance, and the U.S. is just absent," said Jeremy Konyndyk, who worked on the Ebola response in the Obama administration.

Given that no one knows which vaccines will succeed, he said, it's crucial to back multiple efforts working in parallel.

"Against that kind of uncertainty we should be trying to position ourselves to be supporting — and potentially benefiting from — all of them," said Konyndyk, a senior policy fellow at the Center for Global Development. "And instead we seem to be just focused on trying to win the race, in the hopes we happen to get one of the successful ones."

Conference participants expressed a need for unity.

"We can't just have the wealthiest countries have a vaccine and not share it with the world," Canadian Prime Minister Justin Trudeau said.

"Let us in the international community unite to overcome this crisis," Abe said.

Russia and India also did not participate. Chinese premier Li Keqiang was replaced at the last minute by Zhang Ming, Beijing's ambassador to the European Union.

The U.S. official said the United States "is the single largest health and humanitarian donor in world. And the American people have continued that legacy of generosity in the global fight against covid-19."

"And we would welcome additional high-quality, transparent contributions from others," he said.

Asked three more times to explain why the United States did not attend, the official said he already had given an answer.

The U.S. government has provided $775 million in emergency health, humanitarian, economic and development aid for governments, international organizations and charities fighting the pandemic. The official said the United States is in the process of giving about twice that amount in additional funding.

There was one major American player at the virtual summit: the Bill and Melinda Gates Foundation, which promised to spend $125 million in the fight.

"This virus doesn't care what nationality you are," Melinda Gates told the gathering. As long as the virus is somewhere, she said, it's everywhere.

The novel coronavirus is a master of disguise: Here's how it works
The novel coronavirus uses a number of tools to infect our cells and replicate. What we've learned from SARS and MERS can help fight covid-19. (Video: Brian Monroe/Photo: Brian Monroe/The Washington Post)

Scientists are working around-the-clock to find a cure or treatment for the coronavirus. The World Health Organization says eight vaccines have entered human trials and another 94 are in development.

But finding an effective vaccine is only part of the challenge. When it's discovered, infectious disease experts are predicting a scramble for limited doses, because there won't be enough to vaccinate everyone on Day One. And deploying it could be difficult, particularly in countries that lack robust medical infrastructure.

Those that have begun human trials include a research project at Oxford University in England, which hopes to have its vaccine ready in the fall. The university started human trials on April 23. "In normal times," British Health Secretary Matt Hancock said, "reaching this stage would take years."

Other scientists are sprinting to create antiviral drugs or repurposing existing drugs such as remdesivir, which U.S. infectious diseases chief Anthony S. Fauci said he expected would be the new "standard of care."

Other approaches now in trial include treatments such as convalescent plasma, which involves taking blood plasma from people who have recovered from covid-19 to patients who are fighting the virus, in the hope that the antibody-rich fluid will give the infected a helping hand.

Conference participants expressed hope that by working together, the world will find solutions more quickly — and they can then be dispersed to all countries, not only the wealthy, or those that developed vaccines first.

Trump halts funding to WHO for a 'review' of its coronavirus response
President Trump accused the World Health Organization on April 14 of "covering up the spread of the coronavirus." (Photo: Jabin Botsford/The Washington Post)

Many of the leaders stressed their support for the WHO. President Trump announced last month he was cutting off U.S. funding for the WHO because he said it had sided too closely with China, where the coronavirus arose. Trump says Chinese leaders underplayed the threat and hid crucial facts.

Public health analysts have shared some of those criticisms but have also criticized Trump for cutting off funding.

Peter Jay Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine, said the United States has always been the primary funder of new products for global health. The country invested $1.8 billion in neglected diseases in 2018, according to Policy Cures Research, more than two-thirds of the worldwide total.

Hotez said the United States shoulders the burden of investing in global health technologies, while countries such as China do not step up.

“More than one mechanism for supporting global health technologies — that may not be such as a bad thing,” he said. “If it was all under one umbrella, you risk that some strong-willed opinions would carry the day and you might not fund the best technology.”

Hotez is working on a coronavirus vaccine that uses an existing, low-cost technology, previously used for the hepatitis B vaccine, precisely because he is worried about equitable distribution of the vaccine.

“I’m not very confident that some of the cutting-edge technologies going into clinical trials, which have never led to a licensed vaccine before, are going to filter down to low- and middle-income countries anytime soon,” Hotez said. “I’m really worried.”

Stephanie Caccomo
Press Officer

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U.S. Food and Drug Administration
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From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 5/5/2020 8:32:30 AM
To: Baehr, James S. EOP/WHO (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Harrison, William B. EOP/WHO (b)(6); Haves, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Mayberry, Frances A. EOP/NSC (Contractor (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (SBU) Coronavirus Global Response Coordination Unit SitRep No. 148 - 05.05.2020 0630ET.pdf; (U--FOUO) DHS NOC COVID-19 Placemat - 0630 ET 5 May 2020 (NOC-0051-20).pdf; 2020.05.05 CGRCU FactSheet.pdf; daily_report_2020.05.05_CDC.pdf; Early Indicators Daily (04 May 2020).pdf; 20200504-covid-19-sitrep-105_WHO.pdf

Good Morning,

Please find attached various COVID-19 SitReps.

All the best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) (O) **(b)(6)** (cell)
(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/5/2020 9:35:04 AM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: FDA COVID News Digest 5/5/20

Thanks, Molly

From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: May 5, 2020 at 8:58:02 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: FDA COVID News Digest 5/5/20

Dr. Hahn,

Here's today's FDA COVID News Digest (attached and below). We bundled coverage by topic, bolded agency references/quotes and included a quick assessment of the landscape as of this morning. We left in FEMA's hot topics for context. We can adjust to your preference.

Molly

FDA COVID News Digest — May 5, 2020

Media Assessment

- Yesterday's media call and serology policy update dominated FDA coverage across national, regional and trade press.
- Other major headlines of the day include new death estimates from IHME reaching and President Trump's visit to Phoenix.

Serology Policy Update

NBC Nightly News **FDA Increases Oversight Of Coronavirus Antibody Tests. The FDA on Monday "put the brakes on antibody tests." In recent weeks, some 200 such tests have hit the market, but the agency now "says guard rails are needed."**

- Agency Quoted: **"We unfortunately see unscrupulous actors marketing fraudulent test kits to take advantage of Americans."**
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Vaccine

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- Conversation shifted over the course of the day to focus on the release of internal documents that show projections of increasing death rates. The release of these documents is leading many to wonder if the government is being transparent with the information they have.
- As we head into hurricane preparedness week, it is sparking increased debate over whether the agency will be able to handle a major natural disaster and pandemic.
- People are also expressing concern about the lack of social distancing at beaches and other outdoor areas that have reopened leaving people worried a second wave of infections could be around the corner.
- While traditional media remains focused on initial impacts of states reopening, the projected fatality toll has received sharp spike in interest following infection and fatality projections from Institute of Health Metrics and Evaluation as well as a federal interagency document. Tonality is of serious uncertainty.

From: Hurst, Natalie R. EOP/OVP [Natalie.R.Hurst@ovp.eop.gov]
Sent: 5/5/2020 3:07:11 PM
To: Hurst, Natalie R. EOP/OVP [Natalie.R.Hurst@ovp.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; AMA2@HHS.GOV; stm77@treasury.gov; Kudlow, Larry A. EOP/WHO [Lawrence.A.Kudlow@who.eop.gov]; 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 (b)(6); Adams, Jerome (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=302991451fc341bf9a7ffa53eba3f81c-HHS-Jerome.]; BiegunSE@state.gov; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; as1cfw@hq.dhs.gov; Birx, Deborah L. EOP/NSC (b)(6) @cms.hhs.gov; rlw@va.gov; Short, Marc T. EOP/OVP [Marc.T.Short@ovp.eop.gov]; Gershman, Lynn E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=466fe715fb22432e9dcf605736ded877-HHS-veu4-cd]; Pottinger, Matthew F. EOP/WHO (b)(6); Vought, Russell T. EOP/OMB (b)(6); Miller, Katie R. EOP/OVP [Katie.R.Miller@ovp.eop.gov]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Liddell, Christopher P. EOP/WHO (b)(6) Philbin, Patrick F. EOP/WHO (b)(6) Miller, Stephen EOP/WHO [Stephen.Miller@who.eop.gov]; Pete.Gaynor@fema.dhs.gov; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Cipollone, Pat A. EOP/WHO (b)(6); Kellogg, Joseph Keith K. Jr. EOP/OVP (b)(6) Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Pataki, Tim A. EOP/WHO (b)(6) Goyer, Jim L. IV EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6) Hodgson, Christopher M. EOP/OVP (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6) Obenshain, Tucker T. EOP/OVP [(b)(6); Stufft, Julie M. EOP/NSC (b)(6); Kushner, Jared C. EOP/WHO [jck@who.eop.gov]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Joel.Szabat@dot.gov; Philipson, Tomas J. EOP/CEA (b)(6) Conley, Sean P. CDR USN WHMO/WHMU [Sean.Conley@whmo.mil]; Fleming, John C. Jr. EOP/WHO (b)(6) Jacob, Gregory F. EOP/OVP (b)(6) Hicks, Hope C. EOP/WHO [Hope@who.eop.gov]; Fisher, Garrett C. EOP/OVP (b)(6) Nevins, Kristan K. EOP/WHO (b)(6) Sheehan, Matthew J. EOP/OVP (b)(6) O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]; Toland, Scott R. EOP/WHO (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Pinkos, Stephen M. EOP/OVP (b)(6) Stickles, Brendan R. EOP/OVP (b)(6) Dirksen, Ward F. EOP/OVP (b)(6) DL OVP NSA EXECSEC (b)(6) Cavanaugh, Brian J. EOP/NSC [(b)(6) Harris, Shane M. EOP/WHO (b)(6) Ferrer Piran Basualdo, Austin G. EOP/WHO (b)(6) David.Lyons@sd.mil; Anderson-Villaluz, Dennis (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba1863bf2d44fada3b3c8ee83cc63dc-HHS-Dennis.]; Carter, Hillary H. EOP/NSC (b)(6) Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Ash, Deborah J. EOP/NSC (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Davis, May M. EOP/WHO (b)(6) Kan, Derek T. EOP/OMB (b)(6) DeValliere, Ian C. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO (b)(6); Zachary.McEntee@treasury.gov; shirley.gathers@treasury.gov; Andrew.Hughes@hud.gov; Jennifer.L.Naaden@hud.gov; Lin, Merry S. EOP/WHO (b)(6) Baker, Brittany G. EOP/WHO (b)(6) Olmem, Andrew J. EOP/WHO (b)(6) Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]; OVPSchedule (b)(6); BurnettJD@state.gov; HattinghEF@state.gov; Sheehy, Janice

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; julia.bristol@hq.dhs.gov; natalia.best@hq.dhs.gov; Nkosi.thomas@hq.dhs.gov; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Good-Cohn, Meredith (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e06154b83bb4cb8a7b01816905e1300-HHS-Meredit]; Perez-Rivera, Diana (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c224eebfa1e4624b0c22b3b343fe6c7-HHS-Diana.P]; pamela.powers@va.gov; belinda.carrington@va.gov; jacqueline.colli@va.gov; Hennessey, Millicent S. EOP/NSC (b)(6); Conant, Ann M. EOP/OMB (b)(6); Tignor, Beth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f3651e3b164ef786d33dc18b5112a4-HHS-Beth.Ti]; Dareshori, Zachary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3460db40e0d54c918d19bb70b52d8825-HHS-Zachary]; Lair, Kate E. EOP/WHO (b)(6); Riggs, Charlotte R. EOP/WHO (b)(6); Murrell, Baxter R. EOP/WHO (b)(6); Jennifer.Stewart@sd.mil; Rader, John N. EOP/NSC (b)(6); Haley, Vincent M. EOP/WHO (b)(6); Gabriel, Robert Jr. EOP/WHO [Robert.Gabriel@who.eop.gov]; Worthington, Ross P. EOP/WHO (b)(6); Baldwin, Brittany L. EOP/WHO (b)(6); Bolduc, Brian J. EOP/OVP (b)(6); Dumbauld, Cassidy M. EOP/WHO [(b)(6); Hannah.Gonzalez@sd.mil; michael.harrison@sd.mil; anne.powers@sd.mil; Cytryn, Jen B. EOP/WHO [Jennifer.B.Cytryn@who.eop.gov]; McGuffee, Tyler Ann A. EOP/OVP (b)(6); Hahn, Julia A. EOP/WHO (b)(6); Taylor, Elizabeth A. EOP/WHO (b)(6); DL WHO COMMS Speechwriters (b)(6); Ford-Barnes, Arwenthia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenth]; Brunson, Brandy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c990cd3880043fead47cd06152e16e5-HHS-Brandy.]; donna.o'berry@dot.gov; amie.kalsbeek@dot.gov; Nesheiwat, Julia EOP/NSC [(b)(6); lauren.fischer@fema.dhs.gov; Deere, Judd P. EOP/WHO (b)(6); Boyd, Charlton J. EOP/WHO (b)(6); Moore, Caroline E. EOP/WHO [(b)(6); Tubb, Emily A. EOP/CEA (b)(6); Willey, Paige F. EOP/WHO (b)(6); Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Bante, Katie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8abd9d9ceb7c4ebfba6da1cdabb56db4-HHS-Katie.B]; Woolfolk, Jon J. EOP/OVP (b)(6); Myung.Kim@fema.dhs.gov; Gena.lorenz@fema.dhs.gov; rosenfarbch@state.gov; Dittmeier, Kerry W. EOP/OVP (b)(6); Holt, Brandon T. EOP/NSC (b)(6); Earah, Alyssa A. EOP/WHO (b)(6); Gilmartin, Kayleigh M. EOP/WHO (b)(6); Salem-HoweyA@state.gov; Kline, Katherine E. EOP/WHO (b)(6); Trevor, Sarah J. EOP/WHO (b)(6); Hoffman, Austin B. EOP/OMB (b)(6); Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]

CC: Joannou, Tom W. EOP/WHO [(b)(6); Rover, Theodore M. EOP/WHO (b)(6); Rose, Lyndee D. EOP/WHO [(b)(6); Bauer, Zachary C. EOP/OVP (b)(6); Scully, Bethany S. EOP/OVP [(b)(6)

Subject: White House Coronavirus Task Force Meeting

Attachments: IGA COVID-19 Gov Reopen Plans Memo 05-06-2020 Final.pdf; (b)(5); (b)(5); FEMA Request of DOJ voluntary agreement_signed by F1.pdf; Supply Chain Slide 5.6.20.pptx; Post Pandemic Planning Tracker 5-6.pdf (b)(5); (b)(5); (FOUO).pdf; Coronavirus (COVID-19) Update_ Serological Tests _ FDA.pdf; WH JFK Seating Chart 5.6.20.pptx; WH Coronavirus TF Agenda 5.6.20 v2.docx

Location: White House Situation Room

Start: 5/6/2020 4:00:00 PM
End: 5/6/2020 5:00:00 PM
Show Time As: Busy

Importance: High

Recurrence: (none)

All –

There will be a **White House Coronavirus Task Force Meeting** on **Wednesday, May 6th** at **4:00pm** in the White House Situation Room. Materials attached.

Thank you,

Natalie Hurst
Operations Coordinator, White House Coronavirus Task Force
Executive Assistant to the Chief of Staff
The Office of the Vice President
(202) 881-9981

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/6/2020 8:09:47 AM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: FDA COVID News Digest 5/5/20

Thanks Molly and team

From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: May 5, 2020 at 8:58:02 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: FDA COVID News Digest 5/5/20

Dr. Hahn,

Here's today's FDA COVID News Digest (attached and below). We bundled coverage by topic, bolded agency references/quotes and included a quick assessment of the landscape as of this morning. We left in FEMA's hot topics for context. We can adjust to your preference.

Molly

FDA COVID News Digest — May 5, 2020

Media Assessment

- Yesterday's media call and serology policy update dominated FDA coverage across national, regional and trade press.
- Other major headlines of the day include new death estimates from IHME reaching and President Trump's visit to Phoenix.

Serology Policy Update

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- Conversation shifted over the course of the day to focus on the release of internal documents that show projections of increasing death rates. The release of these documents is leading many to wonder if the government is being transparent with the information they have.
- As we head into hurricane preparedness week, it is sparking increased debate over whether the agency will be able to handle a major natural disaster and pandemic.
- People are also expressing concern about the lack of social distancing at beaches and other outdoor areas that have reopened leaving people worried a second wave of infections could be around the corner.
- While traditional media remains focused on initial impacts of states reopening, the projected fatality toll has received sharp spike in interest following infection and fatality projections from Institute of Health Metrics and Evaluation as well as a federal interagency document. Tonality is of serious uncertainty.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/6/2020 8:16:30 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: HHS COVID-19 Update, 5-4-2020

Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: May 6, 2020 at 8:16:12 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: HHS COVID-19 Update, 5-4-2020

Yes Sir, sent to Jim.

Sent from my iPhone

On May 6, 2020, at 8:14 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

This is a nice summary of the recommendations for re-opening. Are we sharing with OO and the small group?
Thanks
Steve

From: Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>
Date: May 4, 2020 at 5:54:23 PM EDT
To: Trueman, Laura (OS) <Laura.Trueman@hhs.gov>
Subject: HHS COVID-19 Update, 5-4-2020

Dear Colleague:

As governors move forward on decisions to reopen some or parts of their states, the Administration continues to support them in a variety of ways. One way is by issuing guidances for the wide range of situations that are part of reopening. We also continue to work closely with states as they solidify their testing and contact tracing capabilities, working individually with them to address their needs. Today's updates fall heavily into these areas.

Testing Updates

Improving Antibody Testing Quality: FDA has revised its policy to improve antibody testing quality. FDA is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to

achieve more rapid and widespread testing capacity in the United States. Under the new policy, FDA expects commercial manufacturers to submit Emergency Use Authorization (EUA) requests, including their validation data, within 10 days of publication of the updated policy or the date they notify FDA of their test validation, whichever is later. Additional information can be found in a fact sheet on antibody testing oversight and use for COVID-19, as well as in a blog posting that notes the new emphasis on prioritizing access and accuracy.

Contact Tracing Training Guidance: CDC released a training module on contact tracing. This web page contains a sample training plan including training topics that may be helpful for state and local public health jurisdictions to consider when designing their own training plan for COVID-19 contact tracers. Each heading represents the learning objective for that section. Suggested training modalities/formats are provided, as well as information about sample existing trainings and resources. This document may be updated as new resources become available.

Information on Evaluation and Testing Patients: CDC updated their guidance on evaluating and testing persons for COVID-19. The changes include updated recommendations for testing, specimen collection, and reporting patients and reporting positive test results, and specification of testing priorities.

CDC Resources for Testing: CDC released a new fact sheet on federal resources for COVID-19 contact tracing staff. This fact sheet describes several ways health departments can access additional staffing for COVID-19 contact tracing, including through State Service Commissions and AmeriCorps Programs, CDC, and FEMA.

Information for Laboratories: CDC updated their FAQ document for testing and reporting by laboratories. The FAQs include information on accessing laboratory testing, data and reporting, test developers, serology, and ordering supplies.

Treatment Updates

Symptom Based Strategy for Discontinuing Isolation: CDC released a decision memo that outlines the updated recommendations for discontinuing isolation. In the context of community transmission where continued testing is impractical, available evidence at this time indicates that an interim strategy based on time-since-illness-onset and time-since-recovery can be implemented to establish the end of isolation. Practical application of a symptom-based strategy cannot prevent all infections.

Updated Information on Discontinuing Isolation: CDC also updated their discontinuation of isolation for persons with COVID-19 not in healthcare settings. This guidance is for healthcare providers and public health officials managing persons with COVID-19 under isolation who are not in healthcare settings. This includes, but is not limited to, at home, in a hotel or dormitory room, or in a group isolation facility. Updates include extending the home isolation period based on evidence suggesting a longer duration of viral shedding and will be revised as additional evidence becomes available. The clinical care guidance for health professionals and information on what to do if you are sick was also updated to reflect this change.

Updates on Convalescent Plasma: The FDA updated its guidance on convalescent plasma and associated web page. The updated guidance provides clarification for investigators on how to submit investigational applications for COVID-19 convalescent plasma. In addition, the guidance includes updated information regarding potential donors. Previously, the FDA's guidance noted that to qualify, individuals should have complete resolution of symptoms for 28 days or resolution for 14 and a negative diagnostic test. The revised guidance recommends that individuals have complete resolution of symptoms for at least 14 days prior to donation. A negative lab test for COVID-19 disease is not necessary to qualify for donation. The revised guidance also clarifies that FDA does not recommend storing a retention sample from the convalescent plasma donation for single patient emergency INDs.

Expanding Dialysis Therapy Options: To help address shortages of continuous renal replacement therapy (CRRT) products during the COVID-19 public health emergency, today the FDA issued an EUA to Fresenius Medical Care for emergency use of the multiFiltrate PRO System and multiBic/multiPlus Solutions. CRRT is a type of dialysis therapy used to filter and clean the blood when the kidneys are damaged or are not functioning normally. The Fresenius multiFiltrate

PRO System and multiBic/multiPlus Solutions have been authorized to provide CRRT to treat patients in an acute care environment during the COVID-19 public health emergency.

Additional Information on Remdesivir: FDA released Frequently Asked Questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients. The FAQs cover EUA for the drug, the side effects, additional information about the uses and the study on Remdesivir and how to obtain the drug.

Convalescent Plasma Guidance and Recommendations: FDA updated their general guidance and recommendations on convalescent plasma. The guidance includes recommendations on pathways for use of plasma, patient eligibility, collection of convalescent plasma, and recordkeeping. Because COVID-19 convalescent plasma has not yet been approved for use by FDA, it is regulated as an investigational product. A health care provider must participate in one of the pathways described below. FDA does not collect COVID-19 convalescent plasma or provide COVID-19 convalescent plasma. Health care providers or acute care facilities should instead obtain COVID-19 convalescent plasma from an FDA-registered blood establishment.

New Study on Coronavirus and Children: NIAID announced a new study to determine incidence of novel coronavirus infection in US children. The study, called Human Epidemiology and Response to SARS-CoV-2 (HEROS), also will help determine what percentage of children infected with SARS-CoV-2, the virus that causes COVID-19, develop symptoms of the disease. In addition, the HEROS study will examine whether rates of SARS-CoV-2 infection differ between children who have asthma or other allergic conditions and children who do not.

PPE and Supplies

PPE Shipments to Nursing Homes: FEMA has released additional details in a fact sheet on PPE shipments to nursing homes. Announced last week, FEMA will coordinate two shipments totaling a 14-day supply of personal protective equipment (PPE) to more than 15,000 nursing homes across the Nation. Shipments are expected to begin in the first week of May and a second shipment will occur in June. Each facility will receive an allotment of surgical masks, gloves, goggles, and gowns. Each facility will receive an allotment of all four items based on the staff size of the facility.

Funding and Resources

$40 Million to Support Education to Racial and Ethnic Minority and Vulnerable Communities: The Office of Minority Health announced a competitive funding opportunity to invest up to $40 million for the development and coordination of a strategic network of national, state, territorial, tribal and local organizations to deliver important COVID-19-related information to racial and ethnic minority, rural and socially vulnerable communities hardest hit by the pandemic. The information network will strengthen efforts to link communities to COVID-19 testing, healthcare and social services and to best share and implement effective response, recovery and resilience strategies. Applications are due by 6:00 PM Eastern Time on Monday, May 11.

30 States Receive Assistance for Crisis Counseling: FEMA announced approval of 30 states and the District of Columbia for its Crisis Counseling Assistance and Training program. The program helps fund state-provided crisis counseling services to residents struggling with stress and anxiety as a result of the coronavirus (COVID-19) pandemic. FEMA's Crisis Counseling program helps people and communities to recover from the effects of natural or man-made disasters through short-term interventions that provide emotional support, crisis counseling, and connection to familial and community support systems.

$200 Million to Local Jurisdictions for Hungry and Homeless Populations: FEMA announced $200 million in supplemental funding allocations to local jurisdictions across the country to supplement local service organizations that provide critical resources to people with economic emergencies, which include our hungry and homeless populations.

Information for General Populations:

COVID-19 At a Glance: The FDA has also posted an updated COVID-19 Response At-A-Glance Summary. It contains updates on major agency activities as well as some important facts and figures.

Tips about Grocery Shopping: Given the many questions people have about grocery shopping safety, the FDA has posted a video, 12 Tips for Grocery Shopping During the Pandemic, to advise consumers.

Information for Specific Populations:

Tips for Healthcare Systems to Operative Effectively: CDC released a new document with 10 ways healthcare systems can operative effectively during the covid-19 pandemic. This document provides practical approaches that can be used to protect healthcare personnel (HCP), patients, and communities. The tips include information on work safety and support, patient service delivery, data streams for situational awareness, facility practices and communications.

Information on Caring for Someone at Home: CDC updated their information on Caring for Someone Sick at Home or other non-healthcare setting. The guidance includes information on how to protect yourself and others. Advice includes learning what to do when someone has symptoms of COVID-19 or when someone has been diagnosed with the virus. This information also should be followed when caring for people who have tested positive but are not showing symptoms.

Information for Pediatric Healthcare Providers: CDC updated their resources for Pediatric Healthcare Providers on what to do when managing pediatric patients with suspected or confirmed COVID-19. The webpage has information on maintaining childhood immunizations during the pandemic, the burden of COVID-19 among children, the clinical presentation of COVID-19 in children, treatment and prevention for children, and additional resources.

Information for Businesses: CDC updated their FAQ document for businesses. The FAQs cover topics including suspected or confirmed cases in the workplace, reducing the spread in workplaces, healthy business operations, cleaning and disinfecting, critical infrastructure and additional resources.

Information for Dentists: CDC updated their infection prevention and control guidance for dental settings during the COVID-19 response. The key information notes that dental settings have unique characteristics that warrant additional infection control considerations and advises dentists to postpone elective procedures, surgeries, and non-urgent dental visits, proactively communicate to both staff and patients the need for them to stay at home if sick, and know steps to take if a patient with COVID-19 symptoms enters your facility. CDC recommends dentists actively screen patients and colleagues before every shift.

Information for Community and Faith-based Organizations: CDC updated their information for community and faith-based organizations in preparations for re-opening. The resources include information on ongoing mitigation guidance, prevention and support, and a webinar.

Information for Veterinarians regarding Companion Animals: CDC updated their interim infection prevention and control guidance for veterinary clinics treating companion animals during the covid-19 response. Updates were made to clarify PPE recommendations based on situational risk factors and guidance for returning to normal clinic practices.

Information for Environmental Health Practitioners: CDC posted information for specific environmental health practitioners including congregate facilities and shelters such as general population disaster shelters, correctional and detention facilities, retirement communities, childcare centers that remain open, cooling centers and more. This webpage provides information for environmental health practitioners from CDC and other trusted sources.

If you have questions, email Gary.Beck@hhs.gov.

Laura

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
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200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov
202-690-6060 (main office)

From: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]
Sent: 5/6/2020 9:42:56 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: FDA COVID News Digest 5/6/20
Attachments: FDA COVID News Digest 5.6.20.docx

Dr. Hahn,

Here's today's FDA COVID News Digest (attached and below). We bundled coverage by topic, bolded agency references/quotes and included a quick assessment of the landscape as of this morning. We left in FEMA's hot topics for context. We can adjust to your preference.

Molly

FDA COVID News Digest — May 6, 2020

Media Assessment

- Hot topics for FDA coverage include news that the White House Task Force is coming to a close, possibly as soon Memorial Day, and next week's Hill appearance.
- News narratives has shifted from testing to vaccine development.

Diagnostics

Politico **White House's "Unorthodox Team" Credited For Surge In US Coronavirus Testing.** "A coalition of administration technocrats, career civil servants and private-sector volunteers who were rapidly thrown together...has become the heart of White House efforts to conquer the all-consuming problem of producing enough tests to safely reopen the economy this month. That unorthodox team, assembled by White House senior adviser Jared Kushner, has achieved real progress: They've revamped medical supply chains, solved ventilator shortages and then devised a Covid-19 testing plan that the White House announced last week. National testing numbers have surged from a meager 5,000 tests on the day the team was assembled to more than 300,000 tests conducted last Friday." Some of the team's efforts include making Assistant Secretary for Health Adm. Brett Giroir the new testing coordinator and **meeting with outside experts such as former FDA Commissioner Scott Gottlieb on testing projections.**

Personal Protective Equipment

Bloomberg Law **HHS Awaiting FDA Approval To Buy 10 Million "Reusable" N95s Masks.** HHS "bought 10 million 'reusable' N95 respirators on condition that those **masks receive emergency use authorization by the FDA, according to an HHS spokesperson. The contract lists the respirators as having a 14-day reusability." However, the respirators "are only approved for single use by the FDA." "A request is being submitted to the FDA for an emergency use authorization to allow the Nexera respirators to be reused."**

- Agency Quoted: **An FDA spokesperson "said they couldn't provide specific information on the emergency use authorization submission because it is considered confidential commercial information."**

Vaccines

Reuters **White House Considering Shutting Down Coronavirus Task Force.** "The focus is now on therapeutics, vaccines and addressing infection hot spots, the task force members said." **HHS Secretary Alex Azar and FDA Commissioner Stephen**

Hahn "said the Trump administration was committed to accelerating the search for a vaccine, with the goal of producing 100 million doses by the autumn and 300 million doses by the end of the year."

USA Today **Scientists Increasingly Considering Challenge Trials Amid Pandemic.** Current regulations "are meant to protect" vaccine trial "volunteers from harm, but with the global death count from the coronavirus over 250,000, scientists are asking: Is it acceptable to deliberately infect healthy people with a disease that could kill them, and for which there is no cure?"

- Agency Quoted: **FDA spokesman Michael Felberbaum said, "A formal determination about any specific human challenge trial proposal would be made by the FDA in the context of all the information that is available at that time."**

Therapeutics

STAT **Gilead Sciences Faces Important Decision After FDA's Emergency Authorization For Use Of Its Drug Remdesivir To Treat Patients With COVID-19.** The position of Gilead Sciences, the maker of remdesivir, which the **FDA has given emergency authorization to for the treatment of COVID-19. Dr**. Anthony Fauci, director of the NIAID, "is sounding close to buoyant" about the drug. STAT recounts an episode that occurred **earlier this year when the FDA granted remdesivir orphan drug status, but the company later asked the agency to rescind the status following criticism of the decision.**

USA Today **Whistleblower Says His Warnings About COVID-19, Hydroxychloroquine Were Ignored.** "HHS political leadership retaliated against Dr. Bright for his objections and resistance to funding potentially dangerous drugs promoted by those with political connections and by the administration itself."

- Additional Coverage: Bloomberg Bright's complaint "outlines his concerns over contracts he says HHS officials pushed based on political considerations rather than scientific data." The complaint states, "Dr. Bright opposed the broad use of chloroquine and hydroxychloroquine as lacking scientific merit…even though the Administration promoted it as a panacea and demanded that New York and New Jersey be 'flooded' with these drugs, which were imported from factories in Pakistan and India that had not been inspected" by US drug regulators.
- Politico: HHS "have disputed his accusation, saying he signed off on the request for the **FDA to authorize emergency use of the drug in late March**."

Drugs

Newsweek **Opinion: Departure Of U.S. Drug Manufacturing To China Has Literally Cost Lives.** The departure of American pharmaceutical manufacturing overseas "has left the U.S. dangerously exposed," and "has literally cost us lives. **While domestic drug production is rightly kept high-quality through unannounced FDA inspections**, international factories producing API, especially Chinese factories, operate without fear of an inspector knocking at the door any minute; visas must be processed well in advance for FDA inspectors visiting factories there, so inspections are scheduled well in advance."

FEMA Hot Topics

- Masks are becoming an increasing hot issue. People are pushing back more about the idea of wearing masks and face coverings while in public spaces.
- Traditional news coverage today remains focused on recent COVID-19 case and fatality projections, including new mentions of a Johns Hopkins epidemiologist clarifying the interagency document of concern was not an official outlook of expected deaths.

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 5/8/2020 9:09:12 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Draft remarks for AAM board meeting
Attachments: 2020-05-11 AAM Board Meeting Hahn remarks.1.docx

Importance: High

Sir—

Attached are draft remarks for your review for the AAM Board meeting on Monday, May 11.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/8/2020 12:35:14 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: FDA COVID News Digest 5/8/20

Thanks, Molly

From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: May 8, 2020 at 10:01:05 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FDA COVID News Digest 5/8/20

Dr. Hahn,

Here's today's FDA COVID News Digest (attached and below). We bundled coverage by topic, bolded agency references/quotes and included a quick assessment of the landscape as of this morning. We left in FEMA's hot topics for context. We can adjust to your preference.

Molly

FDA COVID News Digest — May 8, 2020

Media Assessment

- Two main narratives in the media yesterday include the distribution of the 1.5 million doses of Remdesivir donated to the government, which has been met with much confusion and frustration, and blocked CDC guidance on reopening public spaces.
- Yesterday's announcement updating the EUA for Chinese manufactured KN95 respirators received fair and positive coverage.

Diagnostics

New York Times **FDA Releases New Guidelines For Developing, Marketing At-Home Coronavirus Diagnostic Tests.** The **FDA "has posted new guidelines that could pave the way for millions of people to test themselves for the coronavirus at home."** The guidelines "allow companies to develop and market testing kits with the tools to swab their noses and mail the specimens to any lab in the country." The agency "said it hoped the new guidelines, posted on its site on Wednesday evening, would greatly boost the availability of tests by encouraging manufacturers to mass-produce at-home collection kits." Experts not involved in the guidelines "said they were optimistic about the prospects for home testing, but questioned whether the country's commercial labs could process a deluge of self-collected samples."

Washington Post **FDA Authorizes CRISPR-Based Diagnostic Tool For Coronavirus. "The FDA on Thursday approved a new diagnostic tool that employs the revolutionary CRISPR gene-editing technology to determine in just one hour if someone is infected with the novel coronavirus. The FDA's emergency use authorization allows only 'high-complexity' laboratories to use the test kit**, developed by researchers at the Massachusetts Institute of Technology, Harvard University, the Ragon Institute and the Howard Hughes Medical Institute and marketed by Sherlock Biosciences of Cambridge, Mass."

- Additional Coverage: FierceBiotech "Sherlock did more than 2,000 tests in preparation for its **FDA submission, finding it had 100% specificity and sensitivity in its clinical data**...meaning that it turned up no false positives or false negatives." Meanwhile, "Sherlock is working to ramp up production of the test kit and will unveil distribution plans in the coming weeks."

Wall Street Journal **Scientists Warn Many Coronavirus Antibody Tests Are Not Reliable.** More than 100 coronavirus antibody tests are available in the US, but scientists warn that the tests vary widely in quality and cannot be relied on to determine if a person has immunity to the virus. **The FDA this week also issued warnings about some antibody tests and imposed more stringent rules on manufacturers.**

Vaccines

ABC World News Tonight **First Coronavirus Vaccine In Human Trials Approved For Phase Two.** On Thursday came "a new clue in the war against the coronavirus, as scientists race to develop a vaccine. ... Drug maker Moderna moving at record speed, receiving **FDA approval to advance to phase two of its vaccine study.**"

Personal Protective Equipment

Wall Street Journal **FDA Pulls Approval for Dozens of Mask Makers in China. The FDA said Thursday that it had cut the number of mask makers in China approved to make N95-style masks for use in the U.S. to 14, from around 80.**

- Agency Quoted: **"We've been using all of our authorities to increase availability," an FDA official said in an interview. "There were a growing number of respirators that failed to meet the expedited performance standards."**
- Additional Coverage: Reuters **FDA Withdraws Approval Of Some Chinese Mask Manufacturers To Sell In US. FDA on Thursday announced that it has "canceled the approval for some manufacturers in China to sell N95 respirators in the United States, as they failed to offer adequate protection against the new coronavirus."** The agency indicated the decision was made after "a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95% upon testing."

Therapeutics

Wall Street Journal **Healthcare Leaders Question How Remdesivir Is Being Distributed.** Clinicians are pressuring the Trump administration to explain its criteria for selecting which hospitals get access to Gilead's remdesivir as a COVID-19 treatment. The **FDA authorized remdesivir for emergency use,** but some hospital officials have been told they can't receive the drug since the federal government assumed its allocation.

- Additional Coverage Washington Post physicians have complained that they have yet to see the full clinical trial results and "that cleared the way for the **FDA's emergency authorization of remdesivir** – which means they still don't know which patients stand to benefit the most from the drug." Gilead "said it has enough of the drug to treat up to 140,000 patients, which it has said it is donating for emergency distribution by ASPR and AmerisourceBergen, but that supply is expected to be used up quickly."

Blood Donation

The Hill **Democrats Urge FDA To Lift Restrictions Preventing MSM From Donating Plasma For Research. On Thursday, "the Democrats wrote a letter...to FDA Commissioner Stephen Hahn arguing that keeping men who have sex with men (MSM) from donating plasma undermines efforts to find a treatment for COVID-19."** They said in the letter, "There is no scientific justification for denying MSM who have recovered from coronavirus the opportunity to safely donate plasma. Yet, gay and bisexual men who have recovered from coronavirus and attempted to donate have **been turned away in accordance with FDA's blanket deferral recommendation."**

General News

Washington Examiner **Opinion: Mistakes Made By FDA During AIDS Epidemic Can Be Instructive During COVID-19 Pandemic.** James Driscoll writes, "**FDA's greatest mistake on AIDS was the agency's attempt to delay approval of the**

protease cocktails for three years to more thoroughly test their efficacy. **FDA's risk averse culture has time and again hindered crucial innovation**, and with the coronavirus FDA has become a threat to our economic security."

McClatchy **Health Officials Express Concern FDA Decisions Regarding COVID-19 Treatments, Tests Could Damage Its Credibility. "When the FDA allowed unproven coronavirus antibody tests to go to market in March, without validating their accuracy first," consumer safety experts like former FDA official Regina Barrell "watched as over a dozen different tests reached the public only to produce flawed, unreliable results."** Hydroxychloroquine, a malaria drug touted by President Trump, "was proving harmful to the oldest, most vulnerable victims of the growing pandemic." In response, last week, the **FDA "warned doctors against the use of hydroxychloroquine on coronavirus patients, and on Monday it demanded companies that produce antibody tests prove their effectiveness."**

FEMA Hot Topics

- An increasing number of states are beginning to enter phase one of their reopening plans. Cities are thinking through ways to further help restaurants stay safe while still increasing their business with some considering closing streets to allow increased outdoor seating space.
- There continues to be a high level of skepticism directed at the government and media. People question if death tolls are accurate with people split between feeling numbers are over or under reported. No matter which side people fall on, they often feel numbers are being manipulated to support a given agenda.
- Traditional media coverage has broadly focused on the virus' negative impact on unemployment, PPE distribution updates and fears of federal interference, and potential medical treatments for the virus.
- There is a high volume of discussion regarding reports that the Administration has shelved a CDC document meant to provide guidance on when and how to reopen public spaces.

From: Anderson, Erika [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=98606928B9A64EDFB25ABA1E3573FDFE-ERANDERS]
Sent: 5/11/2020 8:36:43 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
Subject: Re: COVID guidance posting

As an update the guidances and the press release went live this evening.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: May 11, 2020 at 7:15:24 PM EDT
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Subject: Re: COVID guidance posting

Thanks for the information, Erika.
Steve

From: Erika Anderson <Erika.Anderson@fda.hhs.gov>
Date: Monday, May 11, 2020 at 6:19 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>, Karas Gross <Karas.Gross@fda.hhs.gov>, Lowell Schiller <Lowell.Schiller@fda.hhs.gov>, Lauren Roth <Lauren.Roth@fda.hhs.gov>
Subject: COVID guidance posting

Good evening Dr. Hahn,

As we mentioned on the AEG call, there are two guidances that recently cleared OMB. We believe the guidances will post tonight or first thing tomorrow morning. We are confirming timing but wanted to make sure you had a description of these guidances ahead of the hearing.

These two guidances are intended to help accelerate the development of new drug and biological products for COVID-19. The first guidance, *COVID-19: Developing Drugs and Biological Products for Treatment or Prevention*, provides recommendations for conducting clinical trials, including advice on endpoints and study design. The second guidance, *General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products*, helps facilitate the initiation of clinical trials by describing the information needed to support a request to FDA for comments

on a development program. Taken together, the guidances should help sponsors move products into clinical trials more efficiently and may help lead to the review and potential approval of safe and effective drugs and biological products.

If you would like any additional information, just let us know.

Erika

Erika Anderson

Office of Policy, Legislation, and International Affairs
U.S. Food and Drug Administration
Tel: 240-402-4893
erika.anderson@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/12/2020 7:39:56 AM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
Subject: Re: COVID guidance posting

Thanks, Erika

From: Erika Anderson <Erika.Anderson@fda.hhs.gov>
Date: Monday, May 11, 2020 at 8:36 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>, Karas Gross <Karas.Gross@fda.hhs.gov>, Lowell Schiller <Lowell.Schiller@fda.hhs.gov>, Lauren Roth <Lauren.Roth@fda.hhs.gov>
Subject: Re: COVID guidance posting

As an update the guidances and the press release went live this evening.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: May 11, 2020 at 7:15:24 PM EDT
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Subject: Re: COVID guidance posting

Thanks for the information, Erika.
Steve

From: Erika Anderson <Erika.Anderson@fda.hhs.gov>
Date: Monday, May 11, 2020 at 6:19 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>, Karas Gross <Karas.Gross@fda.hhs.gov>, Lowell Schiller <Lowell.Schiller@fda.hhs.gov>, Lauren Roth <Lauren.Roth@fda.hhs.gov>
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Erika

Erika Anderson

Office of Policy, Legislation, and International Affairs
U.S. Food and Drug Administration
Tel 240-402-4893
erika.anderson@fda.hhs.gov

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 5/12/2020 8:18:20 AM
To: Baehr, James S. EOP/WHO (b)(6); Baum, Kristina R. EOP/OSTP (b)(6) Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6) Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6) Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO (b)(6) Clingenpeel, Cale A. EOP/CEA (b)(6) Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6) D'Antuono, Hayley L. EOP/WHO (b)(6) Deere, Judd P. EOP/WHO (b)(6) DeValliere, Ian C. EOP/WHO (b)(6) Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6) DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6) DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6) DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6) Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6) Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6) Goodspeed, Tyler B. EOP/CEA (b)(6) Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Harrison, William B. EOP/WHO (b)(6) Hayes, Bradley F. EOP/OMB (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6) Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6) Johnson, Miles M. EOP/OMB (b)(6); Kan, Derek T. EOP/OMB (b)(6) Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6) Lin, Merry S. EOP/WHO (b)(6) Mayberry, Frances A. EOP/NSC (Contractor) (b)(6) McGuffee, Tyler Ann A. EOP/OVP (b)(6) McKenna, Michael A. EOP/WHO (b)(6) McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6) Miles, Aaron R. EOP/OSTP (b)(6) Moorhead, Quellie U. EOP/WHO (b)(6) Nesheiwat, Julia EOP/NSC (b)(6) Olmem, Andrew J. EOP/WHO (b)(6) Ornato, Tony M. EOP/WHO (b)(6) Pataki, Tim A. EOP/WHO [Timothy.A.Pataki@who.eop.gov]; Philbin, Patrick F. EOP/WHO (b)(6) Pickett, Bethany R. EOP/WHO (b)(6) Pottebaum, Nic D. EOP/WHO (b)(6) Rader, John N. EOP/NSC (b)(6) Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6) Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6) Telle, Adam R. EOP/WHO (b)(6) Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6) Watson, Ian D. EOP/OSTP (b)(6) Willey, Paige F. EOP/WHO (b)(6) Wong, Anna W. EOP/CEA (b)(6) Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SItReps
Attachments: daily_report_2020.05.12_CDC.pdf; (SBU) Coronavirus Global Response Coordination Unit SitRep No. 160 - 05.12.2020 0630ET.doxx.pdf; (U--FOUO) DHS NOC COVID-19 Placemat - 0630 ET 12 May 2020 (NOC-0051-20).pdf; 20200511-covid-19-sitrep-112_WHO.pdf

Dear Colleagues,

Please find attached various COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) cell)
(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/12/2020 8:59:52 AM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: Re: Home testing

thanks

From: Karas Gross <Karas.Gross@fda.hhs.gov>
Date: Tuesday, May 12, 2020 at 8:50 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: Home testing

As of last night, new EUA # is 92, not 85, if you want to update that number.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 12, 2020 8:23 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Re: Home testing

Excellent
thanks

From: Karas Gross <Karas.Gross@fda.hhs.gov>
Date: Tuesday, May 12, 2020 at 8:19 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: Home testing

How is this? Red is new and shows where it can be inserted in the current statement. The second statement is pulled from a press released so it's cleared.

(b)(5)

(b)(5)

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 12, 2020 7:58 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Re: Home testing

No worries at all. I know you've been working overtime on this so I'm sorry to ask.
S

From: Karas Gross <Karas.Gross@fda.hhs.gov>
Date: Tuesday, May 12, 2020 at 7:57 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: Home testing

Of course, sorry I should have offered!

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 12, 2020 7:57 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Re: Home testing

Any chance you could get some wording for me. One or two sentences would suffice. Sorry and thanks
Steve

From: Karas Gross <Karas.Gross@fda.hhs.gov>
Date: Tuesday, May 12, 2020 at 7:50 AM

To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: Home testing

Yes, I think that would be good to highlight.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Tuesday, May 12, 2020 7:39 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Home testing

(b)(5)

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 5/14/2020 7:46:54 AM
To: Baehr, James S. EOP/WHO (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL NSC Africa (b)(6); DL NSC Asia (b)(6); DL NSC BATS (b)(6); DL NSC Defense (b)(6); DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal (b)(6); DL NSC Legislative (b)(6); DL NSC MENA (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC SouthAsia (b)(6); DL NSC STRATCOM (b)(6); DL NSC Visits (b)(6); DL NSC WHA (b)(6); DL NSC WMD (b)(6); DL WHO OLA (b)(6); DL EOP COVID OPS (b)(6); DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) (b)(6); Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Mayberry, Frances A. EOP/NSC (Contractor) (b)(6); McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/ WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (SBU) Coronavirus Global Response Coordination Unit SitRep No. 164 - 05.14.2020 0630ET. .pdf; (U--FOUO) DHS NOC COVID-19 Placemat - 0630 ET 14 May 2020 (NOC-0051-20).pdf; 20200513-covid-19-sitrep-114_WHO.pdf; daily_report_2020.05.14_CDC.pdf

Dear Colleagues,

Please find attached various COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) (O) (b)(6) cell)
(b)(6)

From: Ferro, Phil J. EOP/NSC (b)(6)

Sent: 5/15/2020 8:21:52 AM

To: Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; Campana, Arielia M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6) D'Angelo, Gregory B. EOP/OMB (b)(6) D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6) DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica F. EOP/WHO (b)(6); DL NSC Africa (b)(6) DL NSC Asia (b)(6); DL NSC BATS (b)(6); DL NSC Defense (b)(6); DL NSC EUR (b)(6) DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6) DL NSC Legal (b)(6); DL NSC Legislative (b)(6) DL NSC MENA (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC SouthAsia (b)(6) DL NSC STRATCOM (b)(6); DL NSC Visits (b)(6) DL NSC WHA (b)(6); DL NSC WMD (b)(6) DL WHO OLA (b)(6) DL EOP COVID OPS (b)(6); DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) (b)(6) Galui, Jason J. EOP/CEA (b)(6) Goodspeed, Tyler B. EOP/CEA (b)(6) Harrison, William B. EOP/WHO (b)(6) Hayes, Bradley F. EOP/OME (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6) Kan, Derek T. EOP/OMB (b)(6) Kratsios, Michael J. EOP/OSTP (b)(6) Lattimore, Tra cie BEOP/O STP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Mayberry, Frances A. EOP/NSC (Contractor) (b)(6); McGuffee, Tyler Ann A. EOP/OVP [Tyler.A.McGuffee2@ovp.eop.gov]; McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO [Virginia.D.McMillin@who.eop.gov]; Merkel, Theo W. EOP/WHO (b)(6) Miles, Aaron R. EOP/OSTP (b)(6) Moorhead, Quellie U. EOP/WHO (b)(6) Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6) Ornato, Tony M. EOP/WHO (b)(6) Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO [(b)(6) Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6) Rader, John N. EOP/NSC (b)(6) Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6) Schmoyer, Michael W. EOP/OSTP (b)(6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6) Telle, Adam R. EOP/WHO (b)(6) Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6) Watson, Ian D. EOP/OSTP (b)(6) Willey, Paige F. EOP/WHO [Paige.F.Willey@who.eop.gov]; Wong, Anna W. EOP/CEA [A (b)(6) Ziegler, Garrett M. EOP/WHO (b)(6)

Subject: COVID-19 SitReps

Attachments: (SBU) Coronavirus Global Response Coordination Unit SitRep No. 166 - 05.15.2020 0630ET.pdf; (U--FOUO) DHS NOC COVID-19 Placemat - 0630 ET 15 May 2020 (NOC-0051-20).pdf; 20200514-covid-19-sitrep-115_WHO.pdf; daily_report_2020.05.15_CDC.pdf

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National Security Council
(b)(6) (O) (b)(6) (cell)
(b)(6)

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 5/18/2020 8:24:38 AM
To: Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs. mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); Mayberry, Frances A. EOP/NSC (Contractor) (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 MORNING REPORT 20200518.pdf; (SBU) Coronavirus Global Response Coordination Unit SitRep No. 170 - 05.18.2020 0630ET.pdf; (U--FOUO) DHS NOC COVID-19 Placemat - 0630 ET 18 May 2020 (NOC-0051-20).pdf; 20200517-covid-19-sitrep-118_WHO.pdf

Dear Colleagues,

Please find attached various COVID-19 SitReps.

All the best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) (O **(b)(6)** cell)
(b)(6)

From: Guram, Jeet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EF73BEA97E2B477B847EA302C4730CCF-GURJEET.GUR]
Sent: 5/18/2020 6:30:06 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Flanagan, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15dcaab5c1ea4007adbc43e9acd413a6-Keith.Flana]; Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]; Sager, Nancy B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c2a284a19434f59a27c13e65aabee57-SAGERN]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Burk, Suzann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83015d2cd30a4c62a4e661ac9324f4ee-BurkS]
Subject: Therapeutics/vaccines overview for Sen. Johnson
Attachments: External draft_COVID Therapeutics and Vaccines Update - 20200515.pdf

Dr. Hahn, please see attached a revised version of the COVID-19 therapeutics & vaccines overview with CCI removed; this version has been cleared to be shared with Hill offices. This can be shared without caveats or disclaimers, as it only includes publicly available information. Just let us know if you have any questions or comments.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 5/18/2020 7:53:31 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: RE: CNN--materials
Attachments: topline talkers.docx; CNN_profile of FDA_5.18.20.docx

Updated topline with reactive on DJT taking HCQ. Thanks!

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, May 18, 2020 6:15 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: Re: CNN--materials

Thanks, Stephanie

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: May 18, 2020 at 4:15:09 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>
Subject: CNN--materials

Hi Dr. Hahn:

We've prepared two docs for you, this is also with Frank/Janice.

1. One page topline talkers. Most of the questions fall into 3 "buckets," the bullets should be the toplines you incorporate into your responses. You can have this ready as a quick reference for any out of left field Qs they have.
2. CNN's more specific questions, with brief responses under each Q.

Thanks!

Stephanie Caccomo
Press Officer

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

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/20/2020 8:49:38 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: WH Call TPs for today's state/local call

Laura,
I'll call in for this. The topic 'testing' is pretty broad. What are they expecting specifically from FDA?
Steve

From: Laura Caliguiri <Laura.Caliguiri@fda.hhs.gov>
Date: Wednesday, May 20, 2020 at 8:17 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>
Subject: WH Call TPs for today's state/local call

Sir
Attached and below are your TPs today's call with the White House and state and local leaders. The show flow for the call is below. Note no Q&A. **I understand you will be over there today – would you like me to see if others on the call will be there and where so you can join them?** Laura

THE WHITE HOUSE

COVID-19 IGA State-Local Stakeholder Call

WHEN: Wednesday, May 20, 2020
2:00 p.m. – 3:00 p.m.

DIAL-IN: *Speakers-Only*
Dial-In: 877-369-5243
Code: (b)(6)

PURPOSE: To continue coordination with State and local officials regarding the Administration's response to COVID-19, the implementation of the CARES Act and to provide pertinent Task Force and Agency updates.

AUDIENCE: Approximately ~3,000 State and local elected officials, including Governors/Governor staff, Attorneys General, Secretaries of State, mayors and city councilmembers, county commissioners, law enforcement, and local public health officials.

BACKGROUND: Federal officials have been working diligently to communicate with State, local, and tribal officials on the Federal government's efforts to prepare and respond to COVID-19 and underscore the importance of the partnership at every level of government. Outreach has included national briefing calls with stakeholders, coordination with relevant associations, and significant direct coordination with the most-impacted states and communities. Participants have included the President, Vice President, White House Coronavirus Task Force members, and other Senior Administration Officials.

AGENDA: *Remarks should be kept to approximately 5-10 minutes. There is no Q/A.*

I. Welcome and Introduction

i. Doug Hoelscher, *Deputy Assistant to the President & Director, White House Office of Intergovernmental Affairs (IGA)*

ii. First Lady Melania Trump, *The White House*

II. Testing Update

i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*

ii. Stephen Hahn, *Commissioner, U.S. Food & Drug Administration*

III. Economic and Social Services Support Update

i. Brooke Rollins, *Office of American Innovation*

ii. *TBD*, *Office of Economic Initiatives and Entrepreneurship*

IV. Closing Remarks

May 19, 2020, Talking Points on Serology Testing

(b)(5)

(b)(5)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 5/20/2020 9:26:18 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: <no subject>
Attachments: HQ statement.docx

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/20/2020 9:31:51 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: WH Call TPs for today's state/local call

We are re-working and will send to you in a bit.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, May 20, 2020 8:58 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: WH Call TPs for today's state/local call

Thanks

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: May 20, 2020 at 8:54:37 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: WH Call TPs for today's state/local call

Am mailing the team over there and will call him after the 9.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, May 20, 2020 8:51 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: WH Call TPs for today's state/local call

(b)(5)

Steve

From: Laura Caliguiri <Laura.Caliguiri@fda.hhs.gov>
Date: Wednesday, May 20, 2020 at 8:17 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Colin Rom <Colin.Rom@fda.hhs.gov>
Subject: WH Call TPs for today's state/local call

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   ii. First Lady Melania Trump, *The White House*

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   i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*
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   i. Brooke Rollins, *Office of American Innovation*
   ii. *TBD, Office of Economic Initiatives and Entrepreneurship*

IV. **Closing Remarks**

May 19, 2020, Talking Points on Serology Testing

(b)(5)

(b)(5)

(b)(5)

From: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]
Sent: 5/20/2020 10:41:14 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FDA COVID News Digest 5.20.20
Attachments: FDA COVID News Digest 5.20.20.docx

Dr. Hahn,

Here's today's FDA COVID News Digest (attached and below). We bundled coverage by topic, bolded agency references/quotes and included a quick assessment of the landscape as of this morning. We left in FEMA's hot topics for context. We can adjust to your preference.

Molly

FDA COVID News Digest — May 20, 2020

Media Assessment

- Hydroxychloroquine is still a major topic of discussion in the media.

Testing

Associated Press: **States accused of fudging or bungling COVID-19 testing data**. Public health officials in some states are accused of bungling coronavirus infection statistics or even using a little sleight of hand to deliberately make things look better than they are. In Virginia, Texas and Vermont, for example, officials said they have been combining the results of viral tests, which show an active infection, with antibody tests, which show a past infection. Public health experts say that can make for impressive-looking testing totals but does not give a true picture of how the virus is spreading.

Washington Examiner **Opinion: FDA Blocking Bill Gates-Associated Group From Testing For COVID-19.** "The **FDA has just told a Bill Gates-associated group to stop testing for COVID-19.** Previously unknown cases were being discovered, and the tests being used were more accurate than the ones from the CDC that the **FDA had been insisting everyone must use and only use**."

Houston Chronicle **FDA Grants Austin-Based Company Emergency Clearance For At-Home COVID-19 Testing Kit.** Everlywell "has been **granted emergency clearance by the FDA for an at-home COVID-19 testing kit."** The testing kit "allows a consumer to take a nasal sample at home and send it to a laboratory for the diagnosis," and "will be available later this month for $109 each." The move "**comes after the FDA blocked several companies that have developed at-home testing kits,** including Everlywell, from the market in March over concerns that they would not be administered accurately."

CNBC **Singapore's New Test Kit For Detecting Novel Coronavirus Antibodies Awaits FDA Approval.** (5/20, 3.62M) reports in a video on its site that Singapore's new test kit for detecting coronavirus antibodies in an hour, "which passed regulatory approval in Singapore and the EU," awaits FDA approval. The test is "to confirm if a patient has the infection, says" Duke-NUS Medical School's Emerging Infectious Diseases Program Director Wang Linfa.

Vaccines

STAT **FDA Officials Recuse Themselves From COVID-19 Vaccine Matters. Two top FDA "officials, suddenly at the center of the White House's effort to speed approval for Covid-19 vaccines, will recuse themselves from the agency's**

considerations about whether to approve those products." The inclusion of top FDA brass in the effort almost immediately raised concerns for activists who have long sounded the alarm over industry influence at the FDA." Both Woodcock and Marks will continue as the director of their centers, but will "recuse themselves from the supervisory chain of command in matters related to product review decisions for applications related to the areas that they are advancing that have a nexus to COVID-19," **according to an FDA-wide email sent to staff from Commissioner Stephen Hahn.**

Hydroxychloroquine

CNBC **FDA Commissioner Seems To Soften Agency's Stance On Malaria Drug Trump Says He Is Taking. FDA "said Tuesday that taking hydroxychloroquine is 'ultimately' a choice between patients and their health-care providers, appearing to soften its earlier advisory against taking the anti-malaria drug outside of a hospital."** The comments "came a day after President Donald Trump said he has been taking hydroxychloroquine daily for over a week to prevent infection from the coronavirus."

- Additional Coverage: The Hill

Washington Post **Rubin: Every Republican Supporting Trump's Reelection Is To Blame For Harm That Ensues.** President Trump's statement that he is taking the anti-malaria drug hydroxycholoroquine to stave off COVID-19, **despite his own FDA's warning that such use is dangerous**. "An entire political party fervently backs Trump and wants him to remain in power, propagating goodness knows what for four more years. Trump is not the only menace to public health and safety. Every Republican who tolerates, supports and advocates his reelection is equally to blame for the harm that ensues."

Washington Post **"Fact Checker" Says Trump "Told Half The Story" About Former BARDA Official's Actions On Hydroxychloroquine.** President "Trump sniped at '60 Minutes' for airing an extended interview with Rick Bright, a U.S. vaccine official who alleges that the president's political appointees pressured him to make an untested drug widely available and shuffled him to a new job when he resisted. **Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, urged Bright to request an emergency use authorization (EUA) from the FDA that was far narrower."**

Real World Evidence

Bloomberg Law **FDA To Launch New Research Project Focused On Real-World Evidence To Learn More About COVID-19.** FDA "said Tuesday it's pairing up with the data company Aetion to research Covid-19 complications and what types of medicines virus patients are taking, which could help researchers learn more about which treatments are effective."

- Agency Quoted: **FDA Principal Deputy Commissioner of Food and Drugs Amy Abernethy said in a statement that the partnership with Aetion will add to the data the FDA has already gained through the use of its internal drug monitoring system called Sentinel to "contribute to the scientific evaluation of potential diagnostics and interventions for COVID-19."**
- Additional Coverage: STAT, FierceBiotech

FEMA Hot Topics

- Discussion is primarily focused on the President's comments that he is taking hydroxychloroquine as a preventative measure against COVID-19.
- There also continues to be a large amount of discussion on social media about the President's letter to the World Health Organization, which mentions the possibility of permanently defunding the organization.
- Other subjects of national media interest include the $19 billion in federal aid promised for farmers and agricultural industry, and President Trump's comments on Capitol Hill and during a White House meeting with cabinet secretaries.

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 5/20/2020 11:03:19 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: RE: WH Call TPs for today's state/local call (REVISED)
Attachments: 5.20.20 IGA Call Talkers (revised).docx

Attached and below are your REVISED TPs for today's call and reupping agenda for reading. Hat tip to Molly for stepping in. **(b)(5)**

THE WHITE HOUSE

COVID-19 IGA State-Local Stakeholder Call

WHEN: Wednesday, May 20, 2020
2:00 p.m. – 3:00 p.m.

DIAL-IN: *Speakers-Only*
Dial-In: 877-369-5243
Code **(b)(6)**

PURPOSE: To continue coordination with State and local officials regarding the Administration's response to COVID-19, the implementation of the CARES Act and to provide pertinent Task Force and Agency updates.

AUDIENCE: Approximately ~3,000 State and local elected officials, including Governors/Governor staff, Attorneys General, Secretaries of State, mayors and city councilmembers, county commissioners, law enforcement, and local public health officials.

BACKGROUND: Federal officials have been working diligently to communicate with State, local, and tribal officials on the Federal government's efforts to prepare and respond to COVID-19 and underscore the importance of the partnership at every level of government. Outreach has included national briefing calls with stakeholders, coordination with relevant associations, and significant direct coordination with the most-impacted states and communities. Participants have included the President, Vice President, White House Coronavirus Task Force members, and other Senior Administration Officials.

AGENDA: *Remarks should be kept to approximately 5-10 minutes. There is no Q/A.*

I. **Welcome and Introduction**
   i. Doug Hoelscher, *Deputy Assistant to the President & Director, White House Office of Intergovernmental Affairs (IGA)*
   ii. First Lady Melania Trump, *The White House*

II. **Testing Update**
   i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*
   ii. Stephen Hahn, *Commissioner, U.S. Food & Drug Administration*

III. **Economic and Social Services Support Update**
   i. Brooke Rollins, *Office of American Innovation*
   ii. *TBD*, *Office of Economic Initiatives and Entrepreneurship*

IV. **Closing Remarks**

May 19, 2020, Talking Points on Serology Testing

(b)(5)

(b)(5)

(b)(5)

From: Block, Molly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E32CA68078848889751E7EC26910142-MOLLY.BLOCK]
Sent: 5/20/2020 12:03:44 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: 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: WH Call TPs for today's state/local call (REVISED)
Attachments: 5.20.20 IGA Call Talkers 1145 am.docx

Dr. Hahn,

Please use the updated remarks attached. They should clock in around 6-7 minutes. Please let us know if you have any questions.

Molly

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, May 20, 2020 11:03 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: WH Call TPs for today's state/local call (REVISED)

Attached and below are your REVISED TPs for today's call and reupping agenda for reading. Hat tip to Molly for stepping in. Note no Q&A. You can drop after your remarks.

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(b)(5)

(b)(5)

(b)(5)

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 5/29/2020 8:26:31 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: FDA COVID News Digest 5/29/20

Yessir— on it!

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: May 29, 2020 at 7:56:40 AM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: FDA COVID News Digest 5/29/20

Can you dig into the genome web piece?
Steve

From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: May 29, 2020 at 7:50:35 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FDA COVID News Digest 5/29/20

Here's today's FDA COVID News Digest (attached and below).

Molly

FDA COVID News Digest — May 29, 2020

Media Assessment

- No dominant theme in coverage today. Decent coverage of recent guidances and agency actions including the SARS-CoV-2 reference panel and flexibility under the Produce Safety Rule.

Diagnostic Testing

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- Additional Coverage: Reuters, CNBC, Modern Healthcare

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manufacturers of COVID-19 tests 'unprecedented' flexibility. As we inch toward some semblance of normal and depend on every option to keep us safe, the CDC said antibody tests used to detect if people have been infected in the past with COVID-19 might be wrong up to half the time" and "aren't accurate enough to use in making important policy decisions."

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- Commissioner Quoted: **Similarly, FDA Commissioner Stephen Hahn "warned over Memorial Day weekend that the coronavirus has yet to be contained and that citizens must follow health guidelines to help curb the disease's spread."**

Vaccines

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Food

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- Additional Coverage National Review

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- As more states and local areas reopen, the debate continues about whether face masks should be worn in public. Many schools are beginning to share their plans for resuming classes in the fall, following CDC releasing its guidance last week for schools reopening.
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From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 5/31/2020 2:06:53 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: FDA COVID News Digest 5/29/20

Of course

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: May 31, 2020 at 2:06:31 PM EDT
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Re: FDA COVID News Digest 5/29/20

Very nice. **(b)(5)**
thanks
Steve

From: Colin Rom <Colin.Rom@fda.hhs.gov>
Date: Friday, May 29, 2020 at 1:51 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: FDA COVID News Digest 5/29/20

Little bit of background:

- Reference panels are an additional step to ensure the quality of the tests, validation of new assays, test calibration, and monitoring of assay performance.
- This week, FDA released a reference panel--an independent performance validation step; will provide test developers with well-characterized reagents to compare the performance of different molecular diagnostic tests under the same conditions
- FDA panel is available to commercial and laboratory developers who are interacting with the FDA through the pre-emergency use authorization (EUA) process.
- Nucleic acid tests identify infection by confirming the presence of a virus' genetic material (RNA) and the FDA-supplied reference panel provides developers access to this material.
- FDA has provided similar tools to assist industry in developing tests for other infectious diseases. For example, since the Zika outbreak in 2015, FDA developed and produced reference panels

Here's the press release: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-provides-new-tool-aid-development-and-evaluation-diagnostic-tests

Let me know if there is more info you are thinking about

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, May 29, 2020 7:57 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: FDA COVID News Digest 5/29/20

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From: Block, Molly <Molly.Block@fda.hhs.gov>
Date: May 29, 2020 at 7:50:35 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
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From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/5/2020 2:52:46 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]; Kadakia, Kushal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a10a749d49f9473aa2cd046423ee61bd-Kushal.Kada]
Subject: RE: Preliminary Draft FDA EO
Attachments: smh EO 6.3.20.docx

Steve –
Please see attached draft with tracked edits and comments.
Many thanks to Lowell and Kushal for their joint review
Anand

PRE-DECISIONAL, CONFIDENTIAL

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 6/11/2020 8:04:28 AM
To: Baum, Kristina R. EOP/OSTP (b)(6) Bicket, Mark C. EOP/OSTP (b)(6) Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6) Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6) Campana, Ariella M. EOP/WHO (b)(6) Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6) D'Angelo, Gregory B. EOP/OMB (b)(6) D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6) DeValliere, Ian C. EOP/WHO (b)(6) Dittmeier, Kerry W. EOP/OVP (b)(6) Ditto, Jessica E. EOP/WHO (b)(6) DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6) DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6) DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6) DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6) Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6) Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6) Hayes, Bradley F. EOP/OMB (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6) Jack, Brian T. EOP/WHO (b)(6) Johnson, Miles M. EOP/OMB [James.M.Johnson@omb.eop.gov]; Kan, Derek T. EOP/OMB (b)(6) Kratsios, Michael J. EOP/OSTP (b)(6) Lattimore, Tracie B. EOP/OSTP (b)(6) Lin, Merry S. EOP/WHO (b)(6) McGuffee, Tyler Ann A. EOP/OVP (b)(6) McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6) Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6) Nesheiwat, Julia EOP/NSC (b)(6) Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6) Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6) Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6) Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6) Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6) Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE 20200610_CDC.pdf; (SBU) Coronavirus Global Response Coordination Unit SitRep No. 197 - 06.11.2020 0630ET.pdf; (U--FOUO) DHS NOC COVID-19 Placemat - 0630 ET 11 Jun 2020 (NOC-0051-20).pdf; 20200610-covid-19-sitrep-142_WHO.pdf

Good Morning Colleagues,

Please find attached various COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (O) (b)(6) (cell)
(b)(6)

From: Kimberly, Brad [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08BC909ED76D49868A5FF92C3C70FB72-BRADLEY.KIM]
Sent: 6/11/2020 9:59:28 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: PODCAST NOTES
Attachments: TPs for Podcast v2.docx

Brad Kimberly
Director, Social Media

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/11/2020 10:06:25 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Podcast Dry Run
Attachments: TPs for Podcast v2.docx

Updated TPs

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 6/11/2020 1:41:22 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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: FW: Pipeline Figures
Attachments: Diagnostics Pipeline-0611-1000.jpg; New Drugs Pipeline-0611-1000.jpg; Vaccines Pipeline-0611-1000.jpg; Plasma Products Pipeline-0611-1000.jpg; WHTF 6.11.20.docx; Flu Preparedness Update 5.29.docx; 104_CovidVitals_10 JUNE 2020.docx

Sir--

Attached are background docs for WHTF today. This includes flu preparedness update doc that you wanted on Tuesday just in case. Let me know if there is other info you need.

Thanks!

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 6/11/2020 5:12:47 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: RE: EUA Transparency Project
Attachments: Proposal_for eua transparency project_6.4.20.docx

Here are the talkers and full doc attached.

Talking Points for discussing with Center Directors:

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, June 11, 2020 4:42 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: EUA Transparency Project

Yes sir, will add to agenda for 1-1s. We can discuss with CDER tomorrow.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Thursday, June 11, 2020 4:35 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: EUA Transparency Project

Ok got it. Keagan, I dropped the ball. Let's regroup about these and other issues for the CDs

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: June 11, 2020 at 4:29:34 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: EUA Transparency Project

(b)(5)

(b)(5) Happy to do whatever you wish.

Plan:

(b)(5)

OEA will work to plan rollout of documents.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Thursday, June 11, 2020 1:52 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Re: EUA Transparency Project

I like the transparency and approve moving forward with the caveats that we need to be sensitive to the workload issues. Have the Center Directors been made aware?
Thanks
Steve

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Date: June 11, 2020 at 11:49:59 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: EUA Transparency Project

Thanks for the chat on this today.

Attaching a memo outlining our vision for this EUA transparency project, as well as draft talking points for your discussion with agency leadership.

Thank you!

Stephanie Caccomo
Press Officer

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

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 6/11/2020 9:30:20 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: Baldwin Call Memo
Attachments: Baldwin Meeting Memo 6.12.20.docx

Hi Dr. Hahn-

Attached is a memo for your call tomorrow with Senator Baldwin. I think you have the topic of the call covered, but this includes for your background some of her tweets, press releases and open letters with us. Also, a couple issues that she may raise. I'm also flagging that I won't be on the call tomorrow, but Andy will be and he'll give me a readout. Thanks!

Karas

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 6/12/2020 8:01:26 AM
To: Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO [Robert.B.Blair@who.eop.gov]; Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariell aM. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff [DL.NSC.HSAFOStaff@NSC.eop.gov]; DL NSC IO DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS (b)(6); DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6); Ka n,Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McGuffee,Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE 20200611.pdf; (SBU) Coronavirus Global Response Coordination Unit SitRep No. 198 - 06.12.2020 0630ET.pdf; 20200611-covid-19-sitrep-143_WHO.pdf

Dear Colleagues,

Please find attached CDC, State and WHO COVID-19 SitReps.

Best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (O) (b)(6) (cell)
(b)(6)

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/15/2020 11:28:41 AM
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]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]
Subject: Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

What's the nature of the edits ?

On Jun 15, 2020, at 11:25, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:23 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

From: POLITICO Pro <politicoemail@politicopro.com>
Reply-To: "POLITICO, LLC" <reply-fe881c767362047b72-1158184_HTML-1027883907-1376319-0@politicoemail.com>
Date: Monday, June 15, 2020 at 11:20 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Subject: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

The Food and Drug Administration has withdrawn emergency use authorizations for two controversial coronavirus treatments promoted by President Donald Trump, amid concerns about their safety and effectiveness.

The drugs, hydroxychloroquine and chloroquine, have failed in several recent clinical trials, and doctors say they can cause serious heart problems. The FDA had allowed their use in hospitalized Covid-19 patients and in clinical trials.

To change your alert settings, please go to https://subscriber.politicopro.com/settings.

From: Arbes, Sarah (HHS/ASL) [Sarah.Arbes@hhs.gov]
Sent: 6/15/2020 11:39:41 AM
To: Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; 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: Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Twomey, John K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dabd734e611a472d826cd89d9bc4a352-HHS-John.Tw]; Paden, Maris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e96a29c69e547b9b26163f0e0db4dad-HHS-Maris.P]; Pinson, Alexander (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ecb96fc7294239b8b3d077ed5d219c-HHS-Alexand]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

Hill notification has been sent by FDA OL.

From: Arbes, Sarah (HHS/ASL)
Sent: Monday, June 15, 2020 11:36 AM
To: Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
Cc: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

+ Keagan

From: Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
Sent: Monday, June 15, 2020 11:32 AM
To: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>
Cc: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>
Subject: Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

+Dr Hahn

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:29 AM, Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov> wrote:

+Alex

Agree with Sarah.

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Monday, June 15, 2020 11:29 AM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
Subject: RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

From: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Sent: Monday, June 15, 2020 11:26 AM
To: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
Subject: RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Monday, June 15, 2020 11:23 AM
To: Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>
Subject: Fwd: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

Begin forwarded message:

From: POLITICO Pro <politicoemail@politicopro.com>
Date: June 15, 2020 at 11:20:27 AM EDT
To: "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>
Subject: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

Reply-To: "POLITICO, LLC" <reply-fe881c767362047b72-1158184_HTML-789053134-1376319-0@politicoemail.com>

The Food and Drug Administration has withdrawn emergency use authorizations for two controversial coronavirus treatments promoted by President Donald Trump, amid concerns about their safety and effectiveness.

The drugs, hydroxychloroquine and chloroquine, have failed in several recent clinical trials, and doctors say they can cause serious heart problems. The FDA had allowed their use in hospitalized Covid-19 patients and in clinical trials.

To change your alert settings, please go to https://protect2.fireeye.com/url?k=4484ff6c-18d1f67f-4484ce53-0cc47adb5650-3fb0c90ca6c7b390&u=https://subscriber.politicopro.com/settings.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/15/2020 11:53:17 AM
To: Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Twomey, John K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dabd734e611a472d826cd89d9bc4a352-HHS-John.Tw]; Paden, Maris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e96a29c69e547b9b26163f0e0db4dad-HHS-Maris.P]; Pinson, Alexander (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ecb96fc7294239b8b3d077ed5d219c-HHS-Alexand]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

Michael,
Totally understand.
We will address. We need to do better with coordination.
Steve

From: "Caputo, Michael (HHS/ASPA)" <Michael.Caputo@hhs.gov>
Date: Monday, June 15, 2020 at 11:50 AM
To: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>
Cc: "Arbes, Sarah C (OS)" <Sarah.Arbes@hhs.gov>, "Shuy, Caitrin (OS)" <Caitrin.Shuy@hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>, Ryan Murphy <Ryan.Murphy1@hhs.gov>, "Pence, Laura (OS)" <Laura.Pence@hhs.gov>, Caitlin Oakley <Caitlin.Oakley@HHS.GOV>, "Morse, Sara N (OS)" <Sara.Morse@hhs.gov>, "Twomey, John K (OS)" <John.Twomey@HHS.GOV>, "Paden, Maris (OS)" <Maris.Paden@hhs.gov>, "Pinson, Alexander (OS)" <Alexander.Pinson@hhs.gov>, Karas Gross <Karas.Gross@fda.hhs.gov>
Subject: Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:47 AM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

There are no unethical leakers. The letter and memo posted on the website. (b)(5)

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:35 AM, Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov> wrote:

+ Keagan

From: Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
Sent: Monday, June 15, 2020 11:32 AM
To: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>
Cc: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>
Subject: Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

+Dr Hahn

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:29 AM, Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov> wrote:

+Alex

Agree with Sarah.

From: Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Sent: Monday, June 15, 2020 11:29 AM
To: Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
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<Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
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Subject: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine
Reply-To: "POLITICO, LLC" <reply-fe881c767362047b72-1158184_HTML-789053134-1376319-0@politicoemail.com>

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From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 6/20/2020 10:56:53 AM
To: Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO [Nicholas.D.Pottebaum@who.eop.gov]; Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@hhs.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SItReps
Attachments: 20200619-covid-19-sitrep-151_WHO.pdf; (FOUO) CDC COVID-19 RESPONSE UPDATE 20200619.pdf

Dear Colleagues,

Please find attached CDC and WHO COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (O (b)(6) cell)
Philip.J.Ferro@nsc.eop.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/20/2020 12:55:52 PM
To: Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: Re: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE

Thanks, Mitch

From: Mitchell Zeller <Mitchell.Zeller@fda.hhs.gov>
Date: Saturday, June 20, 2020 at 11:21 AM
To: Stephen Hahn <SH1@fda.hhs.gov>, Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Anna Abram <Anna.Abram@fda.hhs.gov>, Stacy Amin <Stacy.Amin@fda.hhs.gov>, Karas Gross <Karas.Gross@fda.hhs.gov>
Subject: FW: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE

Just making sure everyone has seen this. It came out about an hour ago.

Mitch

From: "NIH OLIB (NIH/OD)" <olib@OD.NIH.GOV>
Date: June 20, 2020 at 10:09:09 AM EDT
To: "NIHPRESS@list.nih.gov" <NIHPRESS@LIST.NIH.GOV>
Subject: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE
Reply-To: "NIH OLIB (NIH/OD)" <olib@OD.NIH.GOV>

U.S. Department of Health and Human Services
NATIONAL INSTITUTES OF HEALTH NIH News
National Heart, Lung, and Blood Institute (NHLBI) <https://www.nhlbi.nih.gov/>
For Immediate Release: Saturday, June 20, 2020

CONTACT: NHLBI Press Office, 301-496-5449, <e-mail:nhlbi news@nhlbi.nih.gov>

NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE
Study shows treatment does no harm, but provides no benefit

WHAT:
A clinical trial to evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with coronavirus disease 2019 (COVID-19) has been stopped by the National Institutes of Health. A data and safety monitoring board (DSMB) met late Friday and determined that while there was no harm, the study drug was very unlikely to be beneficial to hospitalized patients with COVID-19. After its fourth interim analysis the DSMB, which regularly monitors the trial, recommended to the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, to stop

the study. NHLBI halted the trial immediately.

The Outcomes Related to COVID-19 treated with hydroxychloroquine among In-patients with symptomatic Disease study, or ORCHID Study, was being conducted by the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network of NHLBI. The data from this study indicate that this drug provided no additional benefit compared to placebo control for the treatment of COVID-19 in hospitalized patients.

The first participants enrolled in the trial in April at Vanderbilt University Medical Center, Nashville, Tennessee, one of dozens of centers in the PETAL Network. The blinded, placebo-controlled randomized clinical trial aimed to enroll more than 500 adults who are currently hospitalized with COVID-19 or in an emergency department with anticipated hospitalization. More than 470 were enrolled at the time of study's closure.

All participants in the study received clinical care as indicated for their condition. Those randomized to the experimental intervention had also received hydroxychloroquine. Participants in the study will now continue to receive standard of care and follow up as indicated for their condition.

ORCHID participants had been randomly assigned to receive hydroxychloroquine 400 mg twice daily for two doses (day one), then 200 mg twice daily for the subsequent eight doses (days two to five) or a placebo twice daily for five days.

While COVID-19 usually presents as an acute respiratory infection, it can damage multiple organ systems, including heart, lung, and blood. Most adults with COVID-19 experience fever, cough, and fatigue and then recover within one to three weeks. However, some develop severe illness, typically manifesting as pneumonia and respiratory failure, with continued progression to acute respiratory distress syndrome and death.

Hydroxychloroquine is used to treat malaria and rheumatoid conditions such as arthritis. In various studies, the drug had demonstrated antiviral activity, an ability to modify the activity of the immune system, and it has an established safety profile at appropriate doses, leading to the hypothesis that it may have also been useful in the treatment of COVID-19.

WHO:
James P. Kiley, Ph.D., Director, Division of Lung Diseases, NHLBI, is available for interviews.

About the National Heart, Lung, and Blood Institute (NHLBI): NHLBI is the global leader in conducting and supporting research in heart, lung, and blood diseases and sleep disorders that advances scientific knowledge, improves public health, and saves lives. For more information, visit <https://www.nhlbi.nih.gov/>.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <www.nih.gov>.

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This NIH News Release is available online at: <https://www.nih.gov/news-events/news-releases/nih-halts-clinical-trial-hydroxychloroquine>
To subscribe (or unsubscribe) from NIH News Release mailings, go to
<http://service.govdelivery.com/service/subscribe.html?code=USNIH_1>.
If you subscribed via the NIH LISTSERV, go to <https://list.nih.gov/cgi-bin/wa.exe?A0=nihpress>.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/21/2020 8:30:22 AM
To: Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]
Subject: Re: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE

Thx

From: Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>
Date: June 20, 2020 at 3:43:26 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Fwd: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE

FYI

Sent from my iPhone

Begin forwarded message:

From: "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>
Date: June 20, 2020 at 10:35:45 AM EDT
To: "Deere, Judd P. EOP/WHO (Judson.P.Deere@who.eop.gov)" <Judson.P.Deere@who.eop.gov>, "Yanick, Brittany M. EOP/WHO (Brittany.M.Yanick@who.eop.gov)" <Brittany.M.Yanick@who.eop.gov>, "Lyndee.D.Rose@who.eop.gov" <Lyndee.D.Rose@who.eop.gov>
Cc: "Caputo, Michael (HHS/ASPA)" <Michael.Caputo@hhs.gov>
Subject: FW: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE

For your awareness

-----Original Message-----
From: NIH news releases and news items <NIHPRESS@LIST.NIH.GOV> On Behalf Of NIH OLIB (NIH/OD)
Sent: Saturday, June 20, 2020 10:06 AM
To: NIHPRESS@LIST.NIH.GOV
Subject: NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE

U.S. Department of Health and Human Services NATIONAL INSTITUTES OF HEALTH NIH News National Heart, Lung, and Blood Institute (NHLBI) <https://www.nhlbi.nih.gov/> For Immediate Release: Saturday, June 20, 2020

CONTACT: NHLBI Press Office, 301-496-5449, <e-mail:nhlbi_news@nhlbi.nih.gov>

NIH HALTS CLINICAL TRIAL OF HYDROXYCHLOROQUINE Study shows treatment does no harm, but provides no benefit

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A clinical trial to evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with coronavirus disease 2019 (COVID-19) has been stopped by the National Institutes of Health.

A data and safety monitoring board (DSMB) met late Friday and determined that while there was no harm, the study drug was very unlikely to be beneficial to hospitalized patients with COVID-19. After its fourth interim analysis the DSMB, which regularly monitors the trial, recommended to the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, to stop the study. NHLBI halted the trial immediately.

The Outcomes Related to COVID-19 treated with hydroxychloroquine among In-patients with symptomatic Disease study, or ORCHID Study, was being conducted by the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network of NHLBI. The data from this study indicate that this drug provided no additional benefit compared to placebo control for the treatment of COVID-19 in hospitalized patients.

The first participants enrolled in the trial in April at Vanderbilt University Medical Center, Nashville, Tennessee, one of dozens of centers in the PETAL Network. The blinded, placebo-controlled randomized clinical trial aimed to enroll more than 500 adults who are currently hospitalized with COVID-19 or in an emergency department with anticipated hospitalization. More than 470 were enrolled at the time of study's closure.

All participants in the study received clinical care as indicated for their condition. Those randomized to the experimental intervention had also received hydroxychloroquine. Participants in the study will now continue to receive standard of care and follow up as indicated for their condition.

ORCHID participants had been randomly assigned to receive hydroxychloroquine 400 mg twice daily for two doses (day one), then 200 mg twice daily for the subsequent eight doses (days two to five) or a placebo twice daily for five days.

While COVID-19 usually presents as an acute respiratory infection, it can damage multiple organ systems, including heart, lung, and blood. Most adults with COVID-19 experience fever, cough, and fatigue and then recover within one to three weeks. However, some develop severe illness, typically manifesting as pneumonia and respiratory failure, with continued progression to acute respiratory distress syndrome and death.

Hydroxychloroquine is used to treat malaria and rheumatoid conditions such as arthritis. In various studies, the drug had demonstrated antiviral activity, an ability to modify the activity of the immune system, and it has an established safety profile at appropriate doses, leading to the hypothesis that it may have also been useful in the treatment of COVID-19.

WHO:
James P. Kiley, Ph.D., Director, Division of Lung Diseases, NHLBI, is available for interviews.

About the National Heart, Lung, and Blood Institute (NHLBI): NHLBI is the global leader in conducting and supporting research in heart, lung, and blood diseases and sleep disorders that advances scientific knowledge, improves public health, and saves lives. For more information, visit <https://www.nhlbi.nih.gov/>.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <www.nih.gov>.

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This NIH News Release is available online at: <https://www.nih.gov/news-events/news-releases/nih-halts-

clinical-trial-hydroxychloroquine>
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From: Zeller, Mitchell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DE7D2FDA971E418BA33CB211A4013976-MITCHELL.ZE]
Sent: 6/21/2020 11:00:25 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: NYT story and WaPo excerpt

Sending NYT story and the excerpt from today's WaPo story so you have them.

WaPo Excerpt

Amid surging coronavirus infections nationwide, President Trump said at his campaign rally in Tulsa Saturday night that he told officials to administer fewer coronavirus tests to keep case numbers down.

After claiming the United States has tested 25 million people, Trump said: "When you do testing to that extent, you're going to find more people, you're going to find more cases. So I said to my people, 'Slow the testing down, please!' " A White House official later told The Washington Post that Trump was joking.

Eight states on Saturday reported their highest single-day case counts since the pandemic began, and daily new infections nationwide exceeded 30,000 on both Friday and Saturday. The country has not seen daily totals that high in more than seven weeks.

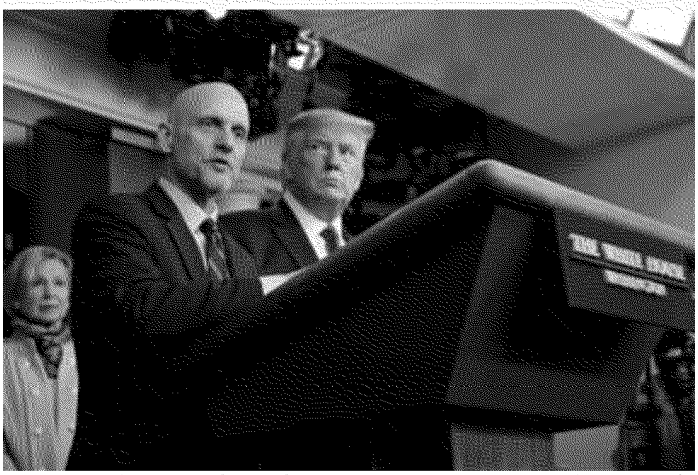
See highlighted portions of NYT story below.

I think the answers we talked through on both stories are credible and defensible.

Mitch

A Mad Scramble to Stock Millions of Malaria Pills, Likely for Nothing

Before the F.D.A. withdrew its waiver to stockpile the drugs as coronavirus treatments, the Trump administration had embarked on a headlong effort to import tens of millions of doses.



Dr. Stephen Hahn, the commissioner of the Food and Drug Administration, at a coronavirus task force briefing with President Trump in March. He will testify before a House committee next week.Credit...Doug Mills/The New York Times

By Sheryl Gay Stolberg

- June 16, 2020

WASHINGTON — The Food and Drug Administration's abrupt decision this week to revoke an emergency waiver for two malaria drugs promoted by President Trump as potential "game changers" against the coronavirus has left 66 million doses stranded in the federal stockpile — and officials do not yet know what they will do with them.

The F.D.A.'s withdrawal on Monday of its "emergency use authorization" for chloroquine and hydroxychloroquine did not go over well at the White House, where top aides to Mr. Trump had rushed in March to fill the federal stockpile. That included accepting a donation from the pharmaceutical giant Bayer of three million tablets from a factory in Pakistan that had not been certified by the F.D.A. as safe.

"This is a Deep State blindside by bureaucrats who hate the administration they work for more than they're concerned about saving American lives," Peter Navarro, Mr. Trump's trade adviser, who helped distribute 19 million hydroxychloroquine pills, fumed in an interview Monday night.

Medical experts across the country — including those who are researching hydroxychloroquine — on Tuesday applauded the F.D.A.'s withdrawal of the waiver after it concluded the drugs' potential benefits did not outweigh their risks.

An F.D.A. spokesman said the White House and Health and Human Services Secretary Alex M. Azar II were made aware of the decision before it was announced. But Mr. Navarro's anger seemed to capture the futility of the administration's headlong efforts to yield to the president's wishes and rush the two drugs into use, yet another example of how politics and science have collided in Mr. Trump's Washington.

Besides Mr. Navarro, the internal debate over the malaria drugs included a well-known cast of characters: Mr. Trump, who took hydroxychloroquine for two weeks and insisted on Monday that it "certainly didn't hurt me"; Dr. Anthony S. Fauci, the government's top infectious disease expert; Rick Bright, who said he was ousted from his position as head of a federal research agency after complaining that Bayer's chloroquine was not safe; and various Fox News personalities.

"They had a flimsy basis for the E.U.A. in the first place," Dr. Peter Lurie, the president of the Center for Science in the Public Interest, said, using the abbreviation for emergency use authorization. "It's quite clear they were strong-armed into it by Navarro himself and others — not excluding radio, television talk show hosts, the president's pals and some doctor in New York. And now they've got mud on their faces because they've belatedly come to their senses and done the right thing."

In the end, none of the chloroquine was ever distributed from the stockpile; doctors preferred hydroxychloroquine, which is newer and has fewer side effects, they say. But its prospects as a treatment for Covid-19 also look dim.

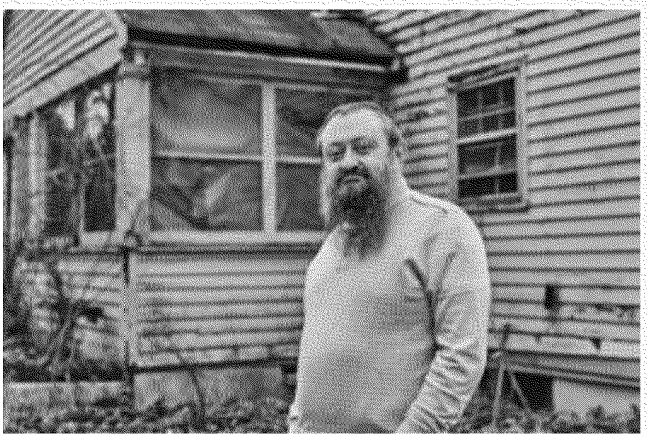
As of Monday, the government has distributed 31 million tablets of hydroxychloroquine to state and local health departments, hospitals and research institutions; 63 million tablets remain, according to Carol Danko, a spokeswoman for the Department of Health and Human Services. Officials are working with the companies that donated the drugs to "determine the available options" for the products.

Dr. Bright, writing on Twitter on Monday night, offered his own idea: "The drugs should never have been brought into our country and should be destroyed. It took far too long for HHS to revoke this EUA."

The frantic effort that led to the F.D.A.'s emergency waiver began in mid-March, just days after Mr. Trump declared the coronavirus pandemic a national emergency, according to emails from Dr. Bright's whistle-blower complaint, some not previously made public, as well as interviews with people involved.

Patients lay dying on gurneys in hospital corridors in New York, governors pleaded with the federal government to send masks and other supplies, and physicians had no treatments. A French doctor, Didier Raoult, stoked interest in hydroxychloroquine with a video promoting it for Covid-19. A cryptocurrency investor, James Todaro, and a New York lawyer, Gregory Rigano, wrote a paper about the drugs, which took off on Twitter, prompting the Fox News host Laura Ingraham to invite Mr. Rigano to appear on her show.

In New York, Dr. Vladimir Zelenko, a self-described "simple country doctor," was giving coronavirus patients a three-drug cocktail that included hydroxychloroquine — and claiming that all had survived without need for hospitalization. (A federal prosecutor recently opened an investigation into Dr. Zelenko's claims.)



Dr. Vladimir Zelenko treated Covid-19 patients with hydroxychloroquine in New York.Credit...Bryan Derballa for The New York Times

With the Republican right, including Ms. Ingraham, Sean Hannity, Tucker Carlson and other Fox News personalities promoting hydroxychloroquine, Mr. Trump chimed in. By March 17, Bayer had offered the White House three million doses of chloroquine, which was discovered in the 1930s and is derived from the bark of the quinine tree.

Some versions of chloroquine are approved in the United States. Bayer's was not. Top officials at Dr. Bright's former agency, known as the Biomedical Advanced Research and Development Authority, or BARDA, were not enthusiastic about the donation; "in vitro," or test tube, studies were not promising, they said.

"Not a lot of enthusiasm based on just vitro data," Robert Johnson, an agency official, wrote in an email to a top aide to Dr. Robert Kadlec, the assistant secretary of health for preparedness and response. "Chloroquine has been shown to have in vitro effects on other microbes, but that has not panned out to clinical benefit."

Dr. Kadlec and his aides, however, were insistent, the emails show. They wanted the chloroquine donation distributed widely as part of a clinical trial that would be sponsored by BARDA, with the National Institutes of Health providing the ethics panel, known as an "institutional review board," overseeing the trial. At the same time, the technology giant Oracle was developing a platform that, the White House hoped, could serve as a vehicle for doctors to enter data about the drug.

On March 23, the F.D.A.'s top lawyer, Stacy Amin, dashed off an urgent email.

"Can we please start moving forward on BARDA sponsoring the chloroquine I.N.D.," she wrote, referring to an "investigational new drug" application, documents that accompany a clinical trial. "The president is announcing this tonight and I believe the W.H. would like it set up by tomorrow with data to flow into the Oracle platform," she added, referring to the White House.

By that time, other companies had donated tens of millions of tablets of hydroxychloroquine, which is approved in the United States and often used to treat lupus, rheumatoid arthritis and other autoimmune disorders, as well as for malaria prevention.

But top F.D.A. officials, as well as Dr. Fauci, took a dim view of the clinical trial idea — and especially the Oracle platform, which they viewed as unworkable, according to three people involved in the decision-making. Dr. Bright, too, was balking; if the drugs had to be accepted into the national stockpile, he wanted their distribution tightly controlled.

Dr. Janet Woodcock, who heads the F.D.A.'s Center for Drug Evaluation and Research, ultimately decided to issue the emergency use authorization, but only for hospitalized patients who could not participate in clinical trials. In a recent interview, Dr. Kadlec said there was no pressure from the White House.

"Everything that was done here was trying to do something consistent with the president's well-established policy of right-to-try and the secretary's efforts to explore every opportunity to find appropriate measures," he said. "Contrary to the recent narrative that said we don't care about science, we do."

The waiver was issued on March 28. Less than a month later, the F.D.A. issued a warning about the drugs, citing "reports of serious heart rhythm problems in patients with Covid-19 treated with hydroxychloroquine or chloroquine."

The Coronavirus Outbreak

In announcing Monday's withdrawal of the waiver, the F.D.A. said its "continued review of the scientific evidence" led officials to conclude that the two drugs are "unlikely to be effective in treating Covid-19" for the uses described in the waiver. That, combined with the concerns about cardiac effects, led to the decision, the agency said.

Representative Greg Walden of Oregon, the top Republican on the House Energy and Commerce Committee, which oversees the F.D.A., expressed support for the decision.

"I trust Dr. Hahn; I think he follows the science," Mr. Walden said, referring to Dr. Stephen Hahn, the F.D.A. commissioner, who will testify before his committee next week. "Emergency use is a powerful tool in his toolbox. Without better data, I think it made sense to turn it off."

The decision does not prevent doctors from prescribing hydroxychloroquine, also available through pharmacies, on their own, though it will probably discourage them from doing so. More than 50 clinical trials — including two large-scale studies conducted by the National Institutes of Health — of hydroxychloroquine are underway in the United States.

Mr. Navarro insisted that the F.D.A. would have "blood on its hands" if any of those studies showed hydroxychloroquine was effective. Dr. Lurie, of the Center for Science in the Public Interest, said the opposite, calling the agency's decision a triumph of "sound science" over "base political instincts."

Dr. Adrian Hernandez, who directs the Clinical Research Institute at Duke University School of Medicine and has enrolled 550 health care workers in a clinical trial to study whether hydroxychloroquine is effective as a prophylactic, agreed. But the controversy over the drug has discouraged participation, he and other researchers have said.

"We should only be using these types of drugs within clinical trials until proven useful," Dr. Hernandez said, adding, "From a policy perspective, the E.U.A. was a complete failure."

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 6/21/2020 11:37:38 AM
To: Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO [Ariella.M.Campana@who.eop.gov]; Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB [(b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO [(b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO [(b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO [(b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE 20200620.pdf; 20200620-covid-19-sitrep-152_WHO.pdf

Dear Colleagues,

Good Morning and Happy Father's Day. Please find attached CDC and WHO COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) (O) (b)(6) (cell)
(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/21/2020 4:38:08 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]
Subject: Hahn opening statement for E&C
Attachments: Hahn E&C opening statement-06-21-20-SMH revisions.docx

Anand and Wayne,
Could you review ASAP and provide comments?
Thanks
Steve

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/21/2020 5:09:16 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]
Subject: RE: Hahn opening statement for E&C
Attachments: as Hahn E&C opening statement-06-21-20-SMH revisions.docx

This is good. My edits are attached.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 21, 2020 4:48 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: Re: Hahn opening statement for E&C

Thanks

From: Anand Shah <Anand.Shah@fda.hhs.gov>
Date: Sunday, June 21, 2020 at 4:45 PM
To: Stephen Hahn <SH1@fda.hhs.gov>, "Pines, Wayne *" <Wayne.Pines@fda.hhs.gov>
Subject: RE: Hahn opening statement for E&C

Reviewing now…

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 21, 2020 4:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: Hahn opening statement for E&C

Anand and Wayne,
Could you review ASAP and provide comments?
Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
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To: Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: Hahn opening statement for E&C
Attachments: as Hahn E&C opening statement-06-21-20-SMH revisions.docx

Will you use Anand's revised version as your starting point?
Thanks
Steve

From: "Pines, Wayne *" <Wayne.Pines@fda.hhs.gov>
Date: Sunday, June 21, 2020 at 5:14 PM
To: Anand Shah <Anand.Shah@fda.hhs.gov>, Stephen Hahn <SH1@fda.hhs.gov>
Subject: RE: Hahn opening statement for E&C

I will send a redline version in a few minutes.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: June 21, 2020 at 5:09:17 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Hahn opening statement for E&C

This is good. My edits are attached.

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 21, 2020 4:48 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: Re: Hahn opening statement for E&C

Thanks

From: Anand Shah <Anand.Shah@fda.hhs.gov>
Date: Sunday, June 21, 2020 at 4:45 PM
To: Stephen Hahn <SH1@fda.hhs.gov>, "Pines, Wayne *" <Wayne.Pines@fda.hhs.gov>
Subject: RE: Hahn opening statement for E&C

Reviewing now…

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Sunday, June 21, 2020 4:38 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: Hahn opening statement for E&C

Anand and Wayne,

Could you review ASAP and provide comments?
Thanks
Steve

From: Pines, Wayne * [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E9F5CE0254041A48966C10D0C38BEF5-WAYNE.PINES]
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To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Fwd: Hahn opening statement for E&C
Attachments: Hahn EC opening statement-06-21-20-SMH revisions.docx

Steve: I made a number of suggested changes in this to punch it up and remove bureaucratic language and also emphasize some critical points. See attached.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/21/2020 6:37:29 PM
To: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Hahn opening statement
Attachments: Hahn EC opening statement-06-21-20-version 3.0.docx

Karas and Colin,
My revisions. If there are any recommended changes to the document by other stakeholders, please let me know. I'll want to see them in track change mode before giving my final sign off. Sound OK?
Thanks
Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/25/2020 12:42:42 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: HCQ talkers

Who created this?

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: June 25, 2020 at 12:18:47 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: HCQ talkers

What do you think?

(b)(5)

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 6/28/2020 9:39:16 AM
To: Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6); Dittmeier, Kerry W. EOP/OVP (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislative [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6); Rollins, Brooke L. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6); Wong, Anna W. EOP/CEA (b)(6); Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE 20200627.pdf; 20200627-covid-19-sitrep-159_WHO.pdf

Good Morning Colleagues,

Please find attached CDC and WHO COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) (O (b)(6) (cell)
(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/28/2020 4:20:58 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
Subject: Revised opening statement
Attachments: HELP Opening Statement-06-30-20-SMH comments.docx

Thanks

From: Kadakia, Kushal [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A10A749D49F9473AA2CD046423EE61BD-KUSHAL.KADA]
Sent: 6/29/2020 12:04:38 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]
Subject: Commissioner Op-Eds -- Consumer, Therapeutics, Vaccine
Attachments: Therapeutics Op-Ed_06.28.2020.docx; Consumer Op-Ed_06.28.2020.docx

Hi Dr. Hahn,

Attached are two draft op-eds based on our conversation this morning: (1) on consumer self-protection/public health guidance in light of recent cases, and (2) on the therapeutic pipeline for COVID-19 and FDA's work in supporting the development of new treatments. All feedback welcome.

In addition to these two op-eds, we also have one on the forthcoming vaccine guidance authored by you and Anand currently in HHS clearance, and another on the state of vaccine development which Wayne drafted this morning. Our goal is to push these through clearance over the next few days.

Let me know what you think, as well any suggestions you might have for additional communications.

Best,
Kushal

Kushal Kadakia
Office of the Commissioner
+1 240 731-3885 | kushal.kadakia@fda.hhs.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/29/2020 2:40:17 PM
To: Kadakia, Kushal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a10a749d49f9473aa2cd046423ee61bd-Kushal.Kada]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]
Subject: Re: Commissioner Op-Eds -- Consumer, Therapeutics, Vaccine
Attachments: Consumer Op-Ed_06.28.2020-SMH comments.docx

Really well done, Kushal. My comments are attached.
Steve

From: "Kadakia, Kushal" <Kushal.Kadakia@fda.hhs.gov>
Date: Monday, June 29, 2020 at 12:04 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Anand Shah <Anand.Shah@fda.hhs.gov>, "Pines, Wayne *" <Wayne.Pines@fda.hhs.gov>, John Wagner <John.Wolf.Wagner@fda.hhs.gov>
Subject: Commissioner Op-Eds -- Consumer, Therapeutics, Vaccine

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Sent: 6/29/2020 3:26:59 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]
Subject: RE: Commissioner Op-Eds -- Consumer, Therapeutics, Vaccine
Attachments: Therapeutics Op-Ed_06.28.2020.docx

Thanks Dr. Hahn! I'll incorporate your comments and work with the team to move it into clearance. I'll also be on the lookout for your feedback on the therapeutics op-ed draft (reattached here for reference).

Best,
Kushal

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 29, 2020 2:40 PM
To: Kadakia, Kushal <Kushal.Kadakia@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Subject: Re: Commissioner Op-Eds -- Consumer, Therapeutics, Vaccine

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From: "Kadakia, Kushal" <Kushal.Kadakia@fda.hhs.gov>
Date: Monday, June 29, 2020 at 12:04 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Anand Shah <Anand.Shah@fda.hhs.gov>, "Pines, Wayne *" <Wayne.Pines@fda.hhs.gov>, John Wagner <John.Wolf.Wagner@fda.hhs.gov>
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From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 6/29/2020 6:23:38 PM
To: Kadakia, Kushal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a10a749d49f9473aa2cd046423ee61bd-Kushal.Kada]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]
Subject: Re: Commissioner Op-Eds -- Consumer, Therapeutics, Vaccine
Attachments: Therapeutics Op-Ed_06.28.2020-SMH comments.docx

Kushal,
My comments on the therapeutics op-ed. Well done.
Steve

From: "Kadakia, Kushal" <Kushal.Kadakia@fda.hhs.gov>
Date: Monday, June 29, 2020 at 12:04 AM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Anand Shah <Anand.Shah@fda.hhs.gov>, "Pines, Wayne *" <Wayne.Pines@fda.hhs.gov>, John Wagner <John.Wolf.Wagner@fda.hhs.gov>
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Kushal

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+1 240 731-3885 | kushal.kadakia@fda.hhs.gov

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 6/29/2020 6:59:02 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: Hearing Prep Materials
Attachments: 20200630_HELPCOVID.Hearing.Day.of.Binder.docx

Binder is attached. Looks like there is likely not much more polling to expect. Karas is following up. Vaccine talkers included as are Alexander POC testing answers as well.

Text me if there is anything else you are seeing is missing and ill track down. Good luck tonight.

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/2/2020 9:15:31 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: talkers for VP trip
Attachments: Vaccine and Therapeutic Talkers 7.2.20.docx

From: Sauer, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FE780AAF3A4448FB18EFDE5E29621D6-ROBERT.SAUE]
Sent: 7/6/2020 9:10:15 AM
To: Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Question
Attachments: Signed: RE: EUA201889 - Becton, Dickinson and Company (BD) - BD Veritor System for Rapid Detection of SARS-CoV-2 EUA Request Package

It was signed July 2nd. I've attached the email with the signed documents.

Robert Sauer
Deputy Director
DPOM: Division of Program Operations and Management | OHT7: Office of In Vitro Diagnostics and Radiological Health
CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 3434 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-3580
Robert.A.Sauer@fda.hhs.gov

From: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Sent: Monday, July 06, 2020 9:05 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Question

Rob, can you please clarify for the Commissioner whether the BD antigen test was signed last week or still pending signature?

From: Hahn, Stephen <SH1@fda.hhs.gov>
Date: July 6, 2020 at 7:17:28 AM EDT
To: Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Question

Elizabeth,
Was the BD antigen Test authorized as an EUA last week or do you expect it this week?
Steve

Sent from my iPad

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 7/7/2020 7:05:16 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: McCarthy Call
Attachments: Hahn Letter 6.15.20.pdf; 2020-2802 RESPONSE.pdf

Flagging this exchange in case it comes up on the call. I can provide more context if you have a couple minutes to chat before the call. Thanks! Karas

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/7/2020 10:37:53 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Fwd: Colin checking in: OC/OEA Homework for Monday 7/6
Attachments: FDA Voices update on CTAP 7.6.20.docx

Sir—

Attached for your review when you have time

FDA Voices - An Update and Behind the Scenes: FDA's Coronavirus Treatment Acceleration Program

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/8/2020 8:17:34 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Two outstanding homework items
Attachments: FDA Voices update on CTAP 7.6.20.docx; immunology statement alexandria.1.docx

Sir—

These are for your review when you have a minute, I know today is packed though:

- FDA Voices - An Update and Behind the Scenes: FDA's Coronavirus Treatment Acceleration Program

- Brief "vision statement" for the Alexandria Summit next week for your review.

Thanks!

From: Steve Daines (b)(6)
Sent: 7/8/2020 11:30:04 AM
To: Steve Daines [sddaines@aol.com]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: Virtual Roundtable event with Senator Daines

Done

On Jul 8, 2020, at 9:03 AM, Steve Daines (b)(6) wrote:

Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable

Title and Location of the Event: Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

Date of the Event: Week of July 13th -- 30 minutes

Points of Contact: Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

Description and Objective: This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

Background on Senator Daines' Work: OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure $10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

Specific Requests: Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

Expected Attendees: 5-8 individuals

Additional Speakers: Senator Daines, hospital leaders, and selected local officials

Open or closed to press? Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/8/2020 11:42:53 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Steve Daines [sddaines@aol.com]
Subject: Re: Virtual Roundtable event with Senator Daines

Thx

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: July 8, 2020 at 9:30:14 AM MDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Steve Daines (b)(6)
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.
Best
Steve

From: Steve Daines (b)(6)
Date: July 8, 2020 at 9:06:05 AM MDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Virtual Roundtable event with Senator Daines

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Sent: 7/8/2020 4:39:32 PM
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Subject: Fwd: Two outstanding homework items
Attachments: immunology statement alexandria.1.docx

Here it is attached!

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Sir—

These are for your review when you have a minute, I know today is packed though:

- FDA Voices - An Update and Behind the Scenes: FDA's Coronavirus Treatment Acceleration Program
- Brief "vision statement" for the Alexandria Summit next week for your review.

Thanks!

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/9/2020 7:57:00 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: COVID Daily
Attachments: COVID Daily 7.9.20.docx

Hey there—

Dr. Hahn mentioned you would be handling the AMA COVID daily. Wanted to make sure you had the daily doc for today in case you need it. Let me know if there is any other info you may need.

Thanks!

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/10/2020 9:22:23 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: COVID Daily 7.10

Ok thx

From: Rom, Colin <Colin.Rom@fda.hhs.gov>
Date: July 10, 2020 at 6:13:30 AM MDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: COVID Daily 7.10

Sir—

Attached is COVID daily. Let me know if there is any more info you might need. Wanted to flag that I spoke to Mary Beth and Patrizia offline abou **(b)(5)** guidance. Patrizia flagged that CDER is considering adding **(b)(5)** that they would likely need a week before finalizing the decision, so it is likely not ripe to share in COVID sync yet.

Thanks!

From: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Sent: 7/12/2020 5:25:45 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Re: talking points on remdescivir

Looks great

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: Sunday, July 12, 2020 at 5:24 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Subject: Re: talking points on remdescivir

FYI. We put together a one pager on therapeutics.
S

From: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Date: Sunday, July 12, 2020 at 5:10 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>
Subject: Re: talking points on remdescivir

Thank you. Perfect.

Sent from my iPhone

On Jul 12, 2020, at 17:09, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Deb,
This looks great. **(b)(5)**
(b)(5)
Steve

From: Debi Birx <Deborah.L.Birx@nsc.eop.gov>
Date: Sunday, July 12, 2020 at 2:00 PM
To: "Miller, Katie R. EOP/OVP" <Katie.R.Miller@ovp.eop.gov>
Cc: Stephen Hahn <SH1@fda.hhs.gov>
Subject: Re: talking points on remdescivir

This month. – ie over the next 30 days

From: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Date: Sunday, July 12, 2020 at 1:59 PM
To: "Miller, Ovp" <Katie.R.Miller@ovp.eop.gov>

Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>
Subject: Re: talking points on remdescivir

51,000 to 90,000 depending on the number of vials needed for treatment course.

From: "Miller, Ovp" <Katie.R.Miller@ovp.eop.gov>
Date: Sunday, July 12, 2020 at 1:55 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Cc: "Hahn, Stephen" <SH1@fda.hhs.gov>
Subject: RE: talking points on remdescivir

Do we have the total number of patients we can treat by chance

---

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Sent: Sunday, July 12, 2020 1:54 PM
To: Miller, Katie R. EOP/OVP <Katie.R.Miller@ovp.eop.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: talking points on remdescivir

Remdesivir

(b)(5)

Steve can you double check wording. All edits welcome.

From: "Miller, Ovp" <Katie.R.Miller@ovp.eop.gov>
Date: Sunday, July 12, 2020 at 1:04 PM
To: "Birx, Deborah L. EOP/NSC" <Deborah.L.Birx@nsc.eop.gov>
Subject: talking points on remdescivir

Do you have that by chance as the take away from Fridays meeting?

From: Alexander, Paul (HHS/ASPA) [Paul.Alexander@hhs.gov]
Sent: 7/13/2020 8:19:17 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: FW: Therapeutics
Attachments: Summary table of COVID studies July 13 for Dr. Hanh and Shah and M Caputo.doc

Hi Dr. Hahn, Anand, and Michael, please see attached a table (as of today's date) of all published studies (RCTs, observational studies, cases series, and systematic reviews) of therapeutics. Many are pre-publications and non-peered; I also include the reference list. On our call today Michael you mentioned a list of therapeutics and I was not sure if it were only what NIH/FDA is involved in or what is being researched and published so far in the research world...this is a list of what has been published as of today globally....

Meplazumab

Ivermectin

Siltuximab

Danoprevir

Tocilizumab (IL-6)

Favipiravir

Darunavir

Nelfinavir

Remdesivir

Chloroquine or hydroxychloroquine

Convalescent plasma

Corticosteroids (dexamethasone etc.)

Arbidol/Umifenovir

Lopinavir/ritonavir

Interferon-alpha

Interferon-beta

heparin (anti-coagulants)

α-Lipoic acid

Ruxolitinib

IVIG

Sarilumab

Famotidine

Lenzilumab

Leflunomide

NSAIDS

Statins

Colchicine

Dr. Paul E. Alexander, PhD
Senior Advisor to the Assistant Secretary
For COVID-19 Pandemic Policy
Office of the Assistant Secretary of Public Affairs (ASPA)
US Department of Health and Human Services (HHS)
Washington, DC
Tel: (202) (b)(6) Office)
Tel (b)(6) Cellular)

Email: paul.alexander@HHS.gov

From: Paul Elias Alexande (b)(6)
Sent: Monday, July 13, 2020 8:04 AM
To: Alexander, Paul (HHS/ASPA) <Paul.Alexander@hhs.gov>
Subject: Therapeutics

Best,

Paul E. Alexander, PhD
Health Research Methodologist, Department of Health Research
Methods, Evidence and Impact,
McMaster University
Assistant Professor
http://hei.mcmaster.ca/
GUIDE Research Methods Group
https://protect2.fireeye.com/url?k=afa9495f-f3fd6074-afa97860-0cc47a6d17cc-ea66e03b087aa83b&u=http://guidecanada.org/

WHO/PAHO Emergency consultant (COVID-19)
Washington, DC.

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 7/13/2020 8:42:06 AM
To: Baum, Kristina R. EOP/OSTP (b)(6) Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Blair, Robert B. EOP/WHO (b)(6) Bonner, Maria K. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OST (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6) Campana, Ariella M. EOP/WHO (b)(6) Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6) D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6) DeValliere, Ian C. EOP/WHO (b)(6) Dittmeier, Kerry W. EOP/OVP (b)(6); DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6) DL NSC HSA FO Staff (b)(6) DL NSC IO (b)(6) DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislativ [DL.Legislative@whmo.mil]; DL NSC MENA (b)(6) DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA (b)(6); DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6); Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6) Harrison, William B. EOP/WHO (b)(6) Hayes, Bradley F. EOP/OMB (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6) Johnson, Miles M. EOP/OMB (b)(6) Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6) Lin, Merry S. EOP/WHO (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6); McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6) Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6) Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6) Ornato, Tony M. EOP/WHO (b)(6) Pataki, Tim A. EOP/WHO (b)(6); Philbin, Patrick F. EOP/WHO (b)(6) Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6) Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6) Rollins, Brooke (b)(6) Schmoyer, Michael W. EOP/OSTP (b)(6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6) Telle, Adam R. EOP/WHO (b)(6) Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP [Paige.E.Waterman@ostp.eop.gov]; Willey, Paige F. EOP/WHO (b)(6) Wong, Anna W. EOP/CEA (b)(6) Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE 20200712.pdf; 20200712-covid-19-sitrep-174_WHO.pdf

Dear Colleagues,

Please find attached CDC and WHO COVID-19 SitReps.

All the best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (O (b)(6) (cell)
(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/13/2020 9:56:47 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: Fwd: Therapeutics one-pager
Attachments: COVID-19 Response Work on Promising COVID-19 Therapeutics.pdf

Are you ok with the information here? Any concerns?

From: Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>
Date: July 13, 2020 at 8:00:11 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Caputo, Michael R (OS) <Michael.Caputo@hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>
Subject: Therapeutics one-pager

(b)(5)

Patrick Brennan
Director of Speechwriting
Department of Health and Human Services
Office: 202-205-2819 | Cel **(b)(6)**

From: Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]
Sent: 7/15/2020 12:53:28 PM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Subject: ***Cleared by ethics***Senator Daines Virtual Roundtable on COVID-19 Vaccine, Update
Attachments: Commissioner External Event Request Form - Senator Daines Request.doc; FW: Hi Keagan, Virtual Roundtable event with Senator Daines; 2020-02-22 Sen. Daines roundtable.docx; Sen. Daines COVID-19 round table background memo - 7-16-20.docx
Location: Virtual/Zoom

Start: 7/22/2020
End: 7/23/2020
Show Time As: Free

From: Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]
Sent: 7/15/2020 12:53:28 PM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Subject: ***Cleared by ethics***Senator Daines Virtual Roundtable on COVID-19 Vaccine, Update
Attachments: Commissioner External Event Request Form - Senator Daines Request.doc; FW: Hi Keagan, Virtual Roundtable event with Senator Daines
Location: Virtual/Zoom

Start: 7/22/2020
End: 7/23/2020
Show Time As: Free

From: Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]
Sent: 7/15/2020 12:53:28 PM
To: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]

Subject: *CANCELED (Dr. Shah did this event)**Cleared by ethics***Senator Daines Virtual Roundtable on COVID-19 Vaccine, Update
Attachments: Commissioner External Event Request Form - Senator Daines Request.doc; FW: Hi Keagan, Virtual Roundtable event with Senator Daines; 2020-02-22 Sen. Daines roundtable.docx; Sen. Daines COVID-19 round table background memo - 7-16-20.docx
Location: Virtual/Zoom

Start: 7/22/2020
End: 7/23/2020
Show Time As: Free

From: SH1@fda.hhs.gov [SH1@fda.hhs.gov]
Sent: 7/16/2020 8:12:02 AM
To: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: Fwd: Talkers for US Chamber
Attachments: 2020-07-16 US Chamber of Commerce Foundation.docx; ATT00001.htm; Resilience Conference Agenda_Final.pdf; ATT00002.htm

Print for me at HHS?
Thanks
Steve

Sent from my iPad

Begin forwarded message:

From: "Rom, Colin" <Colin.Rom@fda.hhs.gov>
Date: July 16, 2020 at 7:56:20 AM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>
Subject: Talkers for US Chamber

Sir—

Here are talkers for Chamber this evening. Sorry for the quick turnaround. Let me know if you have any edits.

Thanks!

From: Alexander, Paul (HHS/ASPA) [Paul.Alexander@hhs.gov]
Sent: 7/18/2020 8:55:36 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
Subject: Corticosteroid RECOVERY trial : dexamethasone
Attachments: nejmoa2021436.pdf

This is the final paper now published of corticosteroid by the Oxford group **(b)(5)**

(b)(5)

Dr. Paul E. Alexander, PhD
Senior Advisor to the Assistant Secretary
For COVID-19 Pandemic Policy
Office of the Assistant Secretary of Public Affairs (ASPA)
US Department of Health and Human Services (HHS)
Washington, DC
Tel: (202) 260-7486 (Office)
Tel: **(b)(6)** Cellular)

Email: paul.alexander@HHS.gov

From: Paul Elias Alexander **(b)(6)**
Sent: Saturday, July 18, 2020 8:32 AM
To: Alexander, Paul (HHS/ASPA) <Paul.Alexander@hhs.gov>
Subject: Corticosteroid RECOVERY trial : dexamethasone

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 7/18/2020 9:33:10 AM
To: Baum, Kristina R. EOP/OSTP (b)(6) Bicket, Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC (b)(6); Blair, Robert B. EOP/WHO (b)(6) Bonner, Maria K. EOP/WHO (b)(6) Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO (b)(6); Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6) DeValliere, Ian C. EOP/WHO (b)(6) Dittmeier, Kerry W. EOP/OVP (b)(6) DL NSC Africa [DL.Africa@whmo.mil]; DL NSC Asia [DL.Asia@whmo.mil]; DL NSC BATS [DL.BATS@whmo.mil]; DL NSC Defense [DL.Defense@whmo.mil]; DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6) DL NSC IO (b)(6); DL NSC Legal [DL.Legal@whmo.mil]; DL NSC Legislativ e[DL.Legislative@whmo.mil]; DL NSC MENA (b)(6); DL NSC NSA FO Staff [DL.NSAFOStaff@whmo.mil]; DL NSC Press [DL.Press@whmo.mil]; DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC SouthAsia [DL.SouthAsia@whmo.mil]; DL NSC STRATCOM [DL.STRATCOM@whmo.mil]; DL NSC Visits [DL.Visits@whmo.mil]; DL NSC WHA [DL.WHA@whmo.mil]; DL NSC WMD [DL.WMD@whmo.mil]; DL WHO OLA [DL.WHO.OLA@WHO.eop.gov]; DL EOP COVID OPS [DL.EOP.COVIDOPS@whmo.mil]; DL Chief of Staff Office (b)(6) Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) [john.j.driscoll24.mil@mail.mil]; Droegemeier, Kelvin K. EOP/OSTP (b)(6) Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) [paul.a.friedrichs.mil@mail.mil]; Galui, Jason J. EOP/CEA (b)(6) Goodspeed, Tyler B. EOP/CEA (b)(6); Harrison, William B. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6) Hudson, Renee R. EOP/WHO (b)(6) Jack, Brian T. EOP/WHO (b)(6); Johnson, Miles M. EOP/OMB (b)(6) Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Latt more, Tracie B. EOP/OSTP (b)(6) Lin, Merry S. EOP/WHO (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6) McKenna, Michael A. EOP/WHO (b)(6); McMillin, Virginia D. EOP/WHO (b)(6) Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6) Moorhead, Quellie U. EOP/WHO (b)(6); Nesheiwat, Julia EOP/NSC (b)(6) Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Phibbin, Patrick F. EOP/WHO (b)(6) Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO (b)(6); Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Reynolds, Lindsay B. EOP/WHO (b)(6) Rollins, Brooke L. EOP/WHO (b)(6); Schmoyer, Michael W. EOP/OSTP (b)(6) Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6); Telle, Adam R. EOP/WHO (b)(6); Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6) Willey, Paige F. EOP/WHO (b)(6) Wong, Anna W. EOP/CEA (b)(6) Ziegler, Garrett M. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE 20200717.pdf; 20200717-covid-19-sitrep-179_WHO.pdf

Dear Colleagues,

Please find attached CDC and WHO COVID-19 SitReps.

Best Regards,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (C (b)(6) cell)
(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/18/2020 4:16:41 PM
To: Alexander, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=562a4dd1dc204fb6b7e447e5e7acfb5f-HHS-Paul.Al]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Re: 1 RCT and 1 opinion on Hydroxychloroquine

Thx Paul

From: Alexander, Paul (HHS/ASPA) <Paul.Alexander@hhs.gov>
Date: July 18, 2020 at 12:18:12 PM MDT
To: Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: 1 RCT and 1 opinion on Hydroxychloroquine

A publication yesterday of HCQ, an RCT and an opinion piece. **(b)(5)**

Dr. Paul E. Alexander, PhD
Senior Advisor to the Assistant Secretary
For COVID-19 Pandemic Policy
Office of the Assistant Secretary of Public Affairs (ASPA)
US Department of Health and Human Services (HHS)
Washington, DC
Tel: (202) 260-7486 (Office)
Tel **(b)(6)** (Cellular)

Email: paul.alexander@HHS.gov

From: Paul Elias Alexander **(b)(6)**
Sent: Saturday, July 18, 2020 2:08 PM
To: Alexander, Paul (HHS/ASPA) <Paul.Alexander@hhs.gov>
Subject: 1 RCT and 1 opinion on Hydroxychloroquine

https://protect2.fireeye.com/url?k=1b369078-47628904-1b36a147-0cc47adc5fa2-81071046fab66788&u=https://www.acpjournals.org/doi/10.7326/M20-4207

Hydroxychloroquine in Nonhospitalized Adults With Early COVID-19. A Randomized Trial
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Original Research

Hydroxychloroquine in Nonhospitalized Adults With Early COVID-19. A Randomized Trial

Editorial

The Saga of Hydroxychloroquine and COVID-19: A Cautionary Tale

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/20/2020 8:05:44 AM
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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: COVID Daily
Attachments: COVID Daily 7.20.20.docx

Keagan—

Attached is today's COVID daily. Let me know if there is any other info you might need.

Thanks!

From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/20/2020 8:11:53 AM
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]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: COVID Daily
Attachments: COVID Daily 7.20.20.docx

Correct— updated attached here

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, July 20, 2020 8:10 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COVID Daily

Though Quest amendment for pooling was authorized this weekend. I think Jeff emailed us that Sat. Can you pls double check?

Sent from my iPhone

On Jul 20, 2020, at 8:05 AM, Rom, Colin <Colin.Rom@fda.hhs.gov> wrote:

Keagan—

Attached is today's COVID daily. Let me know if there is any other info you might need.

Thanks!
<COVID Daily 7.20.20.docx>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/20/2020 11:43:05 AM
To: Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Re: COVID-19 FDA Guidance Tracker - July 20, 2020

Thx Lauren

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Date: July 20, 2020 at 10:50:21 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: COVID-19 FDA Guidance Tracker - July 20, 2020

Commissioner,

Good morning. Below please find today's COVID-19 guidance tracker.

Lauren

From: Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>
Date: July 20, 2020 at 8:44:04 AM EDT
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Agnew, Ann (OS) <Ann.Agnew@hhs.gov>, Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Harrison, Brian (OS) <Brian.Harrison@hhs.gov>, Stecker, Judy (OS) <Judy.Stecker@hhs.gov>, Mango, Paul (OS) <Paul.Mango@hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>, Pence, Laura (OS) <Laura.Pence@hhs.gov>, Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>
Cc: Hawkins, Jamar (OS) <jamar.hawkins@hhs.gov>, Rooths, Tarita <Tarita.Rooths@fda.hhs.gov>, Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>
Subject: COVID-19 FDA Guidance Tracker - July 20, 2020

Documents under HHS review

(No documents to report.)

Documents under OMB review

(b)(5)

Documents Cleared Since Last Tracker

(No documents to report.)

Documents under Development in FDA

On Previous Tracker

(2) CDER, Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency, Questions and Answers

- Provides answers to frequently asked questions about regulatory and policy issues related to inspections, pending drug applications, and changes in manufacturing facilities for approved pharmaceutical products.

(3) CDRH, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)

- Provides a policy to help accelerate the availability of novel coronavirus tests developed by laboratories and commercial manufacturers for the duration of the public health emergency.

(4) CFSAN, Employee Health and Food Safety Checklist for Human and Animal Food Operations During the COVID-19 Pandemic (non-guidance)

- FDA and the Occupational Safety and Health Administration are providing this checklist for FDA-regulated human and animal food operations to use when assessing operations during the COVID-19 pandemic, especially when re-starting operations after a shut down or when reassessing operations because of changes due to the COVID-19 public health emergency caused by the virus SARS-CoV-2.

DELIBERATIVE, INTERNAL, PRE-DECISIONAL

Kenneth R. Cohen, MHSA, MPP
Director, Regulations Policy and Management Staff
Office of Policy
301-796-7001

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/27/2020 11:35:14 AM
To: Stafford, Steven J. EOP/OVP [(b)(6)]
Subject: Hahn remarks
Attachments: Vaccine Site Visits_Remarks_DRAFT_SC_7.26.20.docx

From: Mergy, Jennifer T. EOP/NSC (b)(6)
Sent: 7/27/2020 3:12:58 PM
To: Baum, Kristina R. EOP/OSTP (b)(6) Mark C. EOP/OSTP (b)(6); Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]; Bonyun, Sean C. EOP/OSTP (b)(6) Butterfield, Nicholas W. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; Campana, Ariella M. EOP/WHO (b)(6); Clingenpeel, Cale A. EOP/CEA (b)(6); Crozer, William F. EOP/WHO (b)(6); D'Angelo, Gregory B. EOP/OMB (b)(6); D'Antuono, Hayley L. EOP/WHO (b)(6); Deere, Judd P. EOP/WHO (b)(6); DeValliere, Ian C. EOP/WHO (b)(6) DL NSC Africa (b)(6) DL NSC Asia (b)(6) DL NSC BATS (b)(6) DL NSC Defense (b)(6) DL NSC EUR (b)(6); DL NSC HSA FO Staff (b)(6) DL NSC IO (b)(6) DL NSC Legal (b)(6) DL NSC Legislative (b)(6) DL NSC MENA (b)(6) DL NSC NSA FO Staff (b)(6); DL NSC Press (b)(6) DL NSC Resilience (b)(6) DL N SC SouthAsia (b)(6) DL NSC STRATCOM (b)(6) DL NSC Visits (b)(6); DL NSC WHA (b)(6) DL NSC WMD (b)(6) DL WHO OLA (b)(6); DL EOP COVID OPS (b)(6); DL Chief of Staff Office (b)(6) Driscoll, John J CAPT USCG OSD OUSD POLICY (USA) (b)(6) Droegemeier, Kelvin K. EOP/OSTP (b)(6); Friedrichs, Paul A Brig Gen USAF JS OCJCS (USA) (b)(6); Goodspeed, Tyler B. EOP/CEA (b)(6) Harrison, William B. EOP/WHO (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6) Tavlas, Julia A. EOP/CEA (b)(6) Wiles, Grayson R. EOP/CEA (b)(6); Kan, Derek T. EOP/OMB (b)(6) Kratsios, Michael J. EOP/OSTP (b)(6) Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McGuffee, Tyler Ann A. EOP/OVP (b)(6) McMillin, Virginia D. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6) Miles, Aaron R. EOP/OSTP (b)(6); Moorhead, Quellie U. EOP/WHO (b)(6) Nesheiwat, Julia EOP/NSC (b)(6) Ornato, Tony M. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6) Philbin, Patrick F. EOP/WHO (b)(6); Pickett, Bethany R. EOP/WHO (b)(6); Pottebaum, Nic D. EOP/WHO [Nicholas.D.Pottebaum@who.eop.gov]; Rader, John N. EOP/NSC (b)(6); Redd, Stephen C. EOP/NSC (b)(6); Rollins, Brooke L. EOP/WHO (b)(6) Schmoyer, Michael W. EOP/OSTP (b)(6); Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Storch, Thomas H. EOP/NSC (b)(6) Telle, Adam R. EOP/WHO (b)(6)]; Troye, Olivia EOP/NSC [Olivia.Troye@nsc.eop.gov]; Waterman, Paige E. EOP/OSTP (b)(6); Willey, Paige F. EOP/WHO (b)(6) Wong, Anna W. EOP/CEA (b)(6) Ziegler, Garrett M. EOP/WHO (b)(6) Rader, John N. EOP/WHO (b)(6)
Subject: COVID-19 SitReps
Attachments: 2020 07 24 Science Update_FINAL.pdf; (FOUO) CDC COVID-19 RESPONSE UPDATE 20200727.pdf

Dear Colleagues,

Please find attached today's CDC COVID-19 sitreps.

The latest WHO Situation Reports can be found here.

Best regards,

Jennifer Mergy, Ph.D.
Senior Policy Advisor for Homeland Security and Resilience

National Security Council

(b)(6)

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/28/2020 8:45:21 AM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: Fwd: First Word Alert: Fauci Agrees With FDA, Hydroxychloroquine Not Effective in Covid

Sent from my iPad

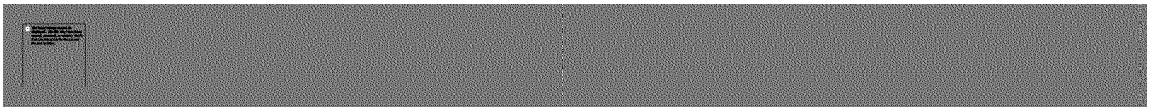
Begin forwarded message:

From: "Zeller, Mitchell" <Mitchell.Zeller@fda.hhs.gov>
Date: July 28, 2020 at 7:46:01 AM EDT
To: "Hahn, Stephen" <SH1@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Wagner, John" <John.Wolf.Wagner@fda.hhs.gov>, "Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>
Subject: FW: First Word Alert: Fauci Agrees With FDA, Hydroxychloroquine Not Effective in Covid

This just in from Bloomberg, in case we get calls.

Mitch

From: Bloomberg Government <alerts@bgov.com>
Sent: Tuesday, July 28, 2020 7:44 AM
To: Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>
Subject: First Word Alert: Fauci Agrees With FDA, Hydroxychloroquine Not Effective in Covid



Fauci Agrees With FDA, Hydroxychloroquine Not Effective in Covid

By Kathleen Miller | July 28, 2020 07:43AM ET | Bloomberg First Word

"The overwhelming prevailing clinical trials that have looked at the efficacy of hydroxychloroquine have indicated that it is not effective in coronavirus disease," NIH infectious disease expert Anthony Fauci says in interview on ABC's "Good Morning America."

- "I go along with the FDA," Fauci says of his position on use of hydroxychloroquine when treating coronavirus
  - Related: Trump Touting Hydroxychloroquine Again Despite FDA Warning

- About Covid vaccine, he says he is “cautiously optimistic that when we get into the late fall we will have an answer”
- Asked if he can do his job when President Trump questions his credibility, Fauci says “I don’t know how to address that. I’m just going to certainly continue to do my job.
  - Fauci says he hasn’t misled the public “under any circumstances”

To contact the reporter on this story:
Kathleen Miller in Washington at kmiller01@bloomberg.net

To contact the editors responsible for this story:
Kasia Klimasinska at kklimasinska@bloomberg.net
Kathleen Miller

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 7/31/2020 12:24:52 PM
To: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Fwd: JAMA - FDA and Vaccines
Attachments: Hahn and Shah FDA Vaccines JAMA_07.30.2020.docx

Print for me?

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: July 31, 2020 at 10:50:44 AM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Kadakia, Kushal <Kushal.Kadakia@fda.hhs.gov>, Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: JAMA - FDA and Vaccines

Steve –
As a follow up to your JAMA event yesterday, here is a JAMA Viewpoint on vaccines.
This has been developed my me and Kushal, and cleared by Peter and OCC
Below is a note for Howard Bauchner
Anand

Howard,
I appreciate the opportunity to speak with you yesterday. As a follow up to the event, please find attached a JAMA Viewpoint submission on vaccines.
It is important for the American people to understand FDA's process and especially our unwavering commitment to safety and effectiveness.
I hope you will consider it for your readers.
Best,
Steve

PRE-DECISIONAL, CONFIDENTIAL

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/8/2020 11:31:13 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: PRO/AH/EDR> Undiagnosed pneumonia - China (HU) (05): novel coronavirus identified

FYI

-----Original Message-----
From: promed-bounces@promedmail.org <promed-bounces@promedmail.org> On Behalf Of promed@promedmail.org
Sent: Wednesday, January 8, 2020 10:30 AM
To: promed-post@promedmail.org; promed-edr-post@promedmail.org; promed-ahead-post@promedmail.org
Subject: PRO/AH/EDR> Undiagnosed pneumonia - China (HU) (05): novel coronavirus identified

UNDIAGNOSED PNEUMONIA - CHINA (HUBEI) (05): NOVEL CORONAVIRUS IDENTIFIED
****

A ProMED-mail post
<http://www.promedmail.org>
ProMED-mail is a program of the
International Society for Infectious Diseases <http://www.isid.org>

Date: Wed 8 Jan 2019
Source: Wall Street Journal
<https://www.wsj.com/articles/new-virus-discovered-by-chinese-scientists-investigating-pneumonia-outbreak-11578485668>

New Virus Discovered by Chinese Scientists Investigating Pneumonia Outbreak Latest tally of people sickened in Wuhan is 59, with 7 in a critical condition
---

Chinese scientists investigating a mystery illness that has sickened dozens in central China have discovered a new strain of coronavirus, a development that will test the country's upgraded capabilities for dealing with unfamiliar infectious diseases.

The novel coronavirus was genetically sequenced from a sample from 1 patient and subsequently found in some of the others affected in the city of Wuhan, according to people familiar with the findings. Chinese authorities haven't concluded that the strain is the underlying cause of sickness in all the patients who have been isolated in Wuhan since the infection 1st broke out in early December [2019], the people said.

There are many known coronaviruses -- some can cause ailments like common colds in humans, while others don't affect humans at all. Some
- such as severe acute respiratory syndrome, or SARS, in 2003 - have led to deadly outbreaks, lending urgency to efforts to contain the current situation.

High Alert
Some past coronavirus outbreaks, such as SARS and MERS, have had high death rates. Yet, there is no suggestion this new illness would cause such issues so far.

	SARS	/	MERS*
Cases:	8098	/	2468
Deaths:	774	/	851
Death rate:	9.6%	/	34.5%
When:	2002-2003	/	2012-
Where first reported:	China	/	Saudi Arabia

*As of September 2019

Sources: Centers for Disease Control and Prevention, World Health Organization

The number of reported cases of viral pneumonia in Wuhan, the capital of Hubei province, was 59 on Sunday, rising from 27 on [31 Dec 2019], according to Wuhan's Municipal Health Commission, with 7 people in a critical condition. No deaths have been reported.

The disease afflicting patients in Wuhan hasn't been transmitted from human to human, and health-care workers have remained uninfected, according to city health officials as of [5 Jan 2020], suggesting that what is sickening them is for now less virulent than SARS. Those ill in Wuhan are believed to have become sick through exposure to animals linked to a live seafood and animal market.

Health experts say one risk is that the disease could become a bigger threat as tens of millions of Chinese travel around the country during the Lunar New Year holidays that begin in just over 2 weeks.

Health authorities in Singapore and Hong Kong, cities that have direct flights from Wuhan, have issued alerts and quarantined patients travelling from the region who show signs of fever or breathing difficulties.

In Hong Kong on Tuesday [7 Jan 2020], the government said it was taking precautions against a "severe respiratory disease associated with a novel infectious agent" that it is seeking to make a statutory notifiable infectious disease, meaning doctors would need to report any suspected cases, and patients evading quarantine could be fined or jailed.

The Chinese Center for Disease Control and Prevention is expected to make an announcement of its findings in the coming days, a person familiar with the matter said. The CDC couldn't be reached for comment late Tuesday [7 Jan 2020].

China was criticized for initially covering up SARS, which was 1st detected in late 2002 but was disclosed only after it began spreading widely, eventually killing 774 people globally, according to the World Health Organization. Beijing overhauled the nation's disease control after reviews found that initial failures to contain and isolate patients with SARS allowed it to proliferate across densely populated Southern China.

The Wuhan outbreak will test how much has changed.
"We learned a bitter lesson in 2003, and we do not want that to happen again," said Alex Lam, chairman of advocacy group Hong Kong Patients'
Voices. "China should immediately release their findings so doctors across the world can better know how to tackle this illness."

Hong Kong's department of health, citing information from China's National Health Commission, said the cause of the cluster of pneumonia cases detected in Wuhan was still under investigation, but other known respiratory pathogens had been ruled out.

The main clinical symptoms of those affected by the Wuhan outbreak are fever - with a few patients having difficulty breathing - and invasive lesions of both lungs, which show up on chest radiographs, the WHO said Sunday [5 Jan 2020].

It is unclear what the underlying source of the disease is, though the reported link to a wholesale fish and live animal market could indicate an exposure link to animals, the WHO said. Bats, for example, are known "reservoirs" for coronaviruses, and have been found to transmit the disease to humans through a third vector such as a civet cat, as scientists found in the case of SARS.

The pattern of the unexplained pneumonia cases linked to the market selling seafood and also live game strongly suggests that this is a novel microbe jumping from animal to human, said K.Y. Yuen, Chair Professor of Infectious Diseases at the University of Hong Kong's Faculty of Medicine.

Researchers have determined that a large proportion of new infectious diseases in humans are transmitted via animals. Such illnesses are referred to as zoonoses. 2 newer human coronaviruses, MERS-CoV and SARS-CoV, have been known to cause severe illness and death, according to the U.S. Centers for Disease Control.

The Wuhan strain is similar to bat coronaviruses that were a precursor to SARS, according to a person familiar with the new findings.

Given the marked advances in hospital isolation facilities, infection-control training and laboratory diagnostic capabilities in the past two decades, it is unlikely that this outbreak will lead to a major 2003-like epidemic, Mr. Yuen said.

In Wuhan, which has China's 1st Biosafety Level 4 laboratory - a specialized research laboratory that deals with potentially deadly infectious agents like Ebola - the market at the center of investigations has been shut down since [1 Jan 2020].

In Hong Kong, badly hit by the SARS virus, which claimed 299 lives locally in 2003, residents have donned surgical masks on the streets and public transport in recent days, despite no local cases of the Wuhan infection being confirmed.

[Byline: Natasha Khan]

--
Communicated by:
ProMED-mail Rapporteur Kunihiko Iizuka
and
Ryan McGinnis
<ryan@digicana.com>

[This is not a surprising finding for all of the reasons stated in previous posts (and speculated there as well). The well known coronaviruses are those that are responsible for the SARS (severe acute respiratory syndrome) and MERS (Middle Eastern Respiratory

Syndrome) outbreaks in 2002-2003 and 2012 to the present respectively (see insert table in media report above.

Coronaviruses belong to the subfamily _Coronavirinae_ in the family _Coronaviridae_, in the order _Nidovirales_. Coronaviruses are enveloped viruses with a positive-sense single-stranded RNA genome and with a nucleocapsid of composed of helical symmetry. There are other human coronaviruses that have been associated with mild upper respiratory symptoms (commonly referred to as the "common cold").

More information on this novel coronavirus from knowledgeable sources would be greatly appreciated.

A map of China showing locations of major cities in China can be found at <https://www.chinadiscovery.com/china-maps/city-maps.html>.

HealthMap/ProMED-mail map of Hubei Province, China:
<http://healthmap.org/promed/p/340>. - Mod.MPP]

[See Also:
Undiagnosed pneumonia - China (HU) (04): Hong Kong surveillance
http://promedmail.org/post/20200106.6874277
Undiagnosed pneumonia - China (HU) (03): updates, SARS, MERS ruled out, WHO, RFI
http://promedmail.org/post/20200105.6872267
Undiagnosed pneumonia - China (02): (HU) updates, other country responses, RFI
http://promedmail.org/post/20200103.6869668
Undiagnosed pneumonia - China (01): (HU) wildlife sales, market closed, RFI
http://promedmail.org/post/20200102.6866757
2019

Undiagnosed pneumonia - China (HU), RFI
http://promedmail.org/post/20191230.6864153]
.....lm/mpp/ml
##
****

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/10/2020 1:30:38 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Update on Undiagnosed Pneumonia - China

Hi. I wanted to provide you with a quick update on the outbreak of pneumonia of unknown cause that is ongoing in Wuhan, China.

Overview:

- There are 59 cases of pneumonia listed as unknown etiology, 7 listed as severe.
- There is a limited clinical picture. Symptom onset of cases is from 12-29 December. Wuhan health officials have not announced any new cases since 05 Jan.
- All known cases are linked to live fish market in Wuhan (closed on 01 December) that also sells other animals.
- There have been no reported health care worker infections or human-to-human transmission.
- 153 known close contacts are being monitored.
- Chinese authorities have made a preliminary determination of a novel coronavirus as the etiologic agent, identified in a hospitalized person with pneumonia in Wuhan
- *Science* is reporting that the "*Two groups isolated the virus from samples from one patient*…[that]…*A total of 15* [of the 59 cases] *were positive for the novel virus, [based on] sequencing samples of [fluid injected into the lung and collected for examination]*…[and that]…*the virus is similar to some of the published* [corona]*viruses collected from bats. But it is not close to SARS and not close to MERS*."
- There has been no known international spread, but many countries in the region have activated protocols to monitor for pneumonia patients of unknown etiology who have recently traveled to China.

WHO Activities:

- WHO is closely monitoring the situation and is in close contact with national authorities in China.
- WHO has requested more information from China on the epidemiological situation and ongoing investigations
- WHO is not currently recommending any specific measures for travelers.
- WHO is developing guidance for member states.
- WHO R&D Blueprint Team held a teleconference on 10 Jan to update members of the Global Coordination Mechanism on the cluster of pneumonia cases and discuss next steps.

USG Activities:

- CDC issued a level 1 travel notice on 06 Jan.
- CDC issued a Health Alert Network notice on 08 Jan.

FDA Activities:

- The FDA Emerging Threats Task Force is monitoring the situation and working to advance and coordinate response activities as necessary.
- The Division of Microbiology (OHT7-OIR/CDRH) is proactively coordinating with CDC on diagnostic activities:
  - DMD had a telecon with CDC on 08 Jan:

- CDC briefed DMD on the current situation and noted that they expect the genetic sequence information to be released soon.
- In anticipation of testing specimens from returning travelers, CDC is developing a molecular test, likely based on the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (which FDA authorized for use under EUA in June 2014 for the presumptive detection of MERS-CoV), that they will CLIA validate for use in their labs.
- From a preparedness standpoint CDC is also planning on submitting a pre-EUA package in case distribution of the test within the Laboratory Response Network is necessary to meet testing demands. DMD is working on an EUA Review template outlining the data requirements for the Pre-EUA package based on previous experience with MERS-CoV.

From: Fisher, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F0CC92E98C4881BD675C3121B343BD-ROBERT.FISH]
Sent: 1/17/2020 10:33:50 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: CCIR & 2019-nCoV (Wuhan)

I'm WAH today….I think most if not all of it can be discussed over the phone if you have time. **(b)(5)**

(b)(5)

Let me know if you'd like me to set up a call through Mayo.

Best,
Robert

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, January 16, 2020 19:38
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Subject: RE: CCIR & 2019-nCoV (Wuhan)

Let's test it. I'm in tomorrow and going to the SCIF if you want to discuss and plan next steps.

Thanks,
Denise

From: Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Sent: Thursday, January 16, 2020 5:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: CCIR & 2019-nCoV (Wuhan)

Hi Denise. Just thinking the Wuhan situation might be a good stress test of the CCIR; **(b)(5)**

(b)(5)

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-796-8518
(m)202-880-2268
robert.fisher@fda.hhs.gov

From: Leiphart, Kristine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F31A911BB5B148F19FE0DF74984A3208-KRISTINE.LE]
Sent: 1/21/2020 2:28:43 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Balog, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44a5f130ddb7411da35b8b49386ca0ae-John.Balog]
Subject: Coronavirus from China

Hi Denise –

Heads up from John Balog: **(b)(5)** **(b)(5)** This is in anticipation of a need to consider an Emergency Use Application (EUA) application.

(b)(5)

Kristine and John

From: Berkower, Ira <Ira.Berkower@fda.hhs.gov>
Sent: Tuesday, January 21, 2020 12:23 PM
To: Balog, John <John.Balog@fda.hhs.gov>
Cc: Murata, Haruhiko (CBER) <Haruhiko.Murata@fda.hhs.gov>
Subject: FW: 2019 n-CoV
Importance: High

Hi John and Haru,

Sorry that I missed the meeting.

Here is some information about the FDA response to the new SARS-like coronavirus currently spreading in China.

I looked up anyone working on SARS currently, as this would be ideal for the new virus.
Unfortunately, I don't see anyone in our IBC system under coronavirus or severe acute resp syndrome. I hope we can work safely with virus and sera at BSL3.

Also, if we receive an IBC application tomorrow, can we discuss it on Thursday?

Best regards,
Ira

From: Weir, Jerry P. <Jerry.Weir@fda.hhs.gov>
Sent: Tuesday, January 21, 2020 11:31 AM
To: Beeler, Judy <Judy.Beeler@fda.hhs.gov>; Berkower, Ira <Ira.Berkower@fda.hhs.gov>; Chumakov, Konstantin <Konstantin.Chumakov@fda.hhs.gov>; Daniels, Robert <Robert.Daniels@fda.hhs.gov>; Golding, Hana <Hana.Golding@fda.hhs.gov>; Khan, Arifa S. <Arifa.Khan@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Levis, Robin <Robin.Levis@fda.hhs.gov>; Lewis, Andrew M. <Andrew.Lewis@fda.hhs.gov>; Major, Marian <Marian.Major@fda.hhs.gov>; Murata, Haruhiko (CBER) <Haruhiko.Murata@fda.hhs.gov>; Parra, Gabriel <Gabriel.Parra@fda.hhs.gov>; Peden, Keith <Keith.Peden@fda.hhs.gov>; Wang, Tony <Tony.Wang@fda.hhs.gov>; Weiss, Carol <Carol.Weiss@fda.hhs.gov>; Ye, Zhiping <Zhiping.Ye@fda.hhs.gov>
Subject: FW: 2019 n-CoV
Importance: High

Please see the email below. This is extremely short notice, but are any of you interested in the novel Coronavirus from China and willing to collaborate with CDRH as outlined in the email below. Notice the BSL-3 needs.
Jerry

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
Sent: Tuesday, January 21, 2020 10:43 AM
To: Weir, Jerry P. <Jerry.Weir@fda.hhs.gov>; Nakhasi, Hira <Hira.Nakhasi@fda.hhs.gov>
Cc: Hobson, John (Peyton) <JOHN.HOBSON@fda.hhs.gov>
Subject: FW: 2019 n-CoV
Importance: High

Dear All,

Apparently, there is a call at noon to discuss whether samples from China should be sent to FDA labs. **(b)(5)**

(b)(5)

Thanks,
Carolyn

From: Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
Sent: Tuesday, January 21, 2020 10:38 AM
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: 2019 n-CoV
Importance: High

Carolyn,

For your information, this is the request we will place. We are only requesting 2 clinical samples to isolate viruses from them or 2 isolates already prepared to further propagate in culture. We only need a small performance panel to evaluate companies that apply for molecular devices.

In the future **(b)(5)**

As explained, **(b)(5)**
(b)(5)

If you cannot provide an investigator name by 11:30 AM, would you mind to be listed as the contact person for CBER for the time being? We need to provide the request to OCET by then.

Thanks for your help and sorry for this last minute request. We did not have much time to plan for this.

Regards,

Mayra

From: Garcia, Mayra
Sent: Saturday, January 18, 2020 5:15 PM
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
Subject: FW: 2019 n-CoV
Importance: High

Carolyn,

My name is Mayra Garcia, I am a former post-doc at Sue Epstein's lab and since 2014 I am working at CDRH, Division of Microbiology Devices. We deal with emergent pathogens and Emergency Use Authorizations from a regulatory point of view. However, after Zika we also have started to prepare sample panels to provide to sponsors who apply for EUAs, in order to be able to compare performance of the devices with a characterized set of samples.

We are looking for labs at CBER that may work on coronavirus and are authorized to get patient samples in case an emergency is declared.

Could you provide any contact information?

Many thanks,

Mayra Garcia, Ph.D., M.B.A.
Scientific Reviewer

Hepatitis and General Virology Branch
Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR) | OHT7

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3602 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 240-402-7213
Mayra.Garcia@fda.hhs.gov

From: Epstein, Suzanne <Suzanne.Epstein@fda.hhs.gov>
Sent: Saturday, January 18, 2020 5:06 PM
To: Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
Subject: RE: 2019 n-CoV

Hi Mayra,

Deborah Taylor used to do coronavirus work, but I don't think she's there any longer. I don't know of anyone else, but I suppose you could ask Carolyn Wilson.

Regards,
Sue

From: Garcia, Mayra <Mayra.Garcia@fda.hhs.gov>
Sent: Saturday, January 18, 2020 5:01 PM
To: Epstein, Suzanne <Suzanne.Epstein@fda.hhs.gov>
Subject: 2019 n-CoV
Importance: High

Sue,

Sorry to bother you. We are looking for labs at CBER that may work on coronavirus and are authorized to get patient samples in case an emergency is declared. Can you think of anyone?

Thanks,

Mayra

From: Simms, Joshua [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9B4D1B8521364CE2B0DCCE89B861B673-JOS]
Sent: 1/21/2020 2:40:46 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; CDER-ER-OPS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4aa67416e2b4b80b0ea03681b334525-CDER-ER-OPS]; CDRH All Hazards Readiness Response and Cybersecurity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af150d41dbea48c2b898c3431c24a132-CDRHEMCM]; Jackson, LeeAnne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=736277c6fd7b486db5807177dc64a362-LJACKSO1]; CVM ECRS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=062b2b538bbf45ecabc711a5d80a680d-CVM ECRS]; Barth, Janelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18d28baf2bfa435abc9cdfa076774dc0-Janelle.Bar]; Yee, James C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16ae6bace74d477bafef3a41a80fb9bc-JC.Yee]; Livsey, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa4fc2e358a43cca8dfd5d4d59f7ab5-KLivsey]; Scire, Nicholas J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64094a38518642ff80d3c4df2ddd164d-NSCIRE]; Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Devore, Nicolette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd9d011e02c45d6b1005d46342cad69-Devore]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Morrison, Ellen F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87bb455186e7484881678218bc601d97-EMORRISO]; Howard King, Vinetta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=483818dd7b704eb1b886a4140c892063-VKing]; Harris, Stic [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1db72edda1ac46b99f4c4ce832b6d999-Orville.Har]; Irvin, Kari [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9fea0d41738d458282b5e0ab147de54d-Kari.Irvin]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]
Subject: URGENT IHR REVIEW REQUIRED: Potential PHEIC - Confirmation of novel coronavirus (nCoV) in the United States
Attachments: USG IHR Event Assessment and Notification Form_v2-SG-cleared.pdf

Good afternoon,

FDA OEO received notification from the HHS International Health Regulations (IHR) Program regarding a potential PHEIC involving the first confirmed novel coronavirus (nCoV). The IHR event notification form is attached.

The HHS/ASPR International Health Regulations (IHR) Program requests FDA's review of the attached pending notification of a potential public health emergency of international concern (PHEIC). Subsequent to this review period, HHS/ASPR will request the approval of the Assistant Secretary for Preparedness and Response, who serves as the IHR Message Authorizing Official, to send this notification to the World Health Organization.

If you have any comments, please advise OEO by **5:00PM EDT today (1/21/2020).**

Event information

The IHR Program has been notified of a potential PHEIC involving a Chinese citizen in the United States who tested positive for nCoV.

Title: Confirmation of novel coronavirus (nCoV)

Location: United States

PHEIC notification criteria met:

Criteria 1- Public health impact of the event is serious
Criteria 2- Event is unusual/unexpected
Criteria 3 –Significant Risk of International Spread
Criteria 4- Significant Risk of Travel or Trade Restrictions

The Centers for Disease Control and Prevention (CDC) is closely monitoring an outbreak caused by a novel (new) coronavirus (nCoV) in Wuhan City, Hubei Province, China. Chinese authorities first identified the new coronavirus, which has resulted in about 200 confirmed human infections and three reported deaths in China. A number of countries, including the United States, are actively screening incoming travelers from Wuhan, and exported cases have been confirmed in Thailand, Japan, and South Korea. The first case confirmed case in the United States was announced on January 21, 2020.

United States Patient Case Summary:
35 year old otherwise healthy male, Chinese citizen, traveled from the United States to Wuhan, China on November 26, 2019. He returned to the United States on January 15, 2020 and began to experience symptoms on January 16, 2020. He had normal chest x-ray and a negative test for influenza virus. He did not report exposure to ill persons, livestock or seafood/animal markets while in China. Due to travel to Wuhan, he was tested for nCoV (and was discharged home with instructions for home isolation). The patient specimen, acquired on January 19, 2020, was sent overnight to CDC and on January 20, 2020 tested positive for nCoV. CDC is actively coordinating with state and local health departments on the response.

Thank you,

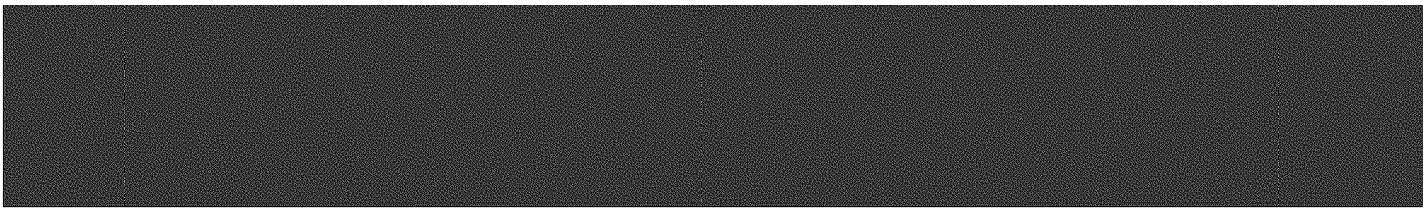
Josh

Joshua Simms
CAPT, U.S. Public Health Service
Director
Office of Emergency Operations
U.S. Food and Drug Administration
Desk: 301-796-5599
Cell: (b)(6)
Email: joshua.simms@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374


FDA
U.S. FOOD & DRUG
ADMINISTRATION

From: Centers for Disease Control and Prevention [no-reply@emailupdates.cdc.gov]
Sent: 1/22/2020 2:07:05 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: CDC Tanzania: Working Together to Save Lives

CDC Around the World



CDC Tanzania: Working Together to Save Lives

January 22, 2019

IN THIS ISSUE

The Centers for Disease Control and Prevention (CDC), under the U.S. Mission to Tanzania, works to strengthen tuberculosis prevention efforts for people living with HIV through the U.S. President's Emergency Plan for AIDS Relief; enhance laboratory, surveillance, and workforce capacity to respond to disease outbreaks through the Global Health Security Agenda; and implement interventions for malaria prevention and control under the U.S. President's Malaria Initiative.

VIEW MORE

FEATURE STORY
A team of five travel to regions with largest numbers of people living with HIV to provide hands-on help for 3 months.

More

BLOG
Five personal stories that highlight CDC's impact in Tanzania and the vital role communities play in controlling and ultimately ending the HIV epidemic.

More

INFOGRAPHIC
CDC is working with Tanzania to leverage strengths in cross-cutting science and data-driven programs to improve the health and lives and people across the country.

More

STORY
Tanzania's Field Epidemiology and Lab Training Program has trained 450 disease detectives in the past 10 years, building frontline capacity to identify and respond to emergency threats.

More

2019 Novel Coronavirus (2019-nCoV), Wuhan, China

The Centers for Disease Control and Prevention (CDC) is closely monitoring an outbreak caused by a novel (new) coronavirus in Wuhan City, Hubei Province, China. There are ongoing investigations to learn more. This is a rapidly evolving situation and information will be updated as it becomes available.

View more resources on CDC Outbreak website >

IN THE NEWS

CDC sends experts to fight measles outbreaks in Pacific islands neighboring Samoa
Washington Post
Dec 11, 2019

CALENDAR

Feb 4 – World Cancer Day

Feb 13 – Five Years of CDC's Global Health Security Accomplishments

CDC Issues Guidance for Use of Tafenoguine for Malaria
Contagion Live
Dec 10, 2019

Global measles cases surge amid stagnating vaccinations
NBC News
Dec 6, 2019

VIEW MORE

Feb 25 – Rare Disease Day

Mar 3 – CDC Response to Ebola in the DRC

NEWS, WEB & SOCIAL MEDIA UPDATES FROM CDC CENTER FOR GLOBAL HEALTH
www.cdc.gov/globalhealth

Follow CDC Global Health on Social Media

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For questions about this newsletter, please email CDCGlobal@cdc.gov
The Center for Global Health. www.cdc.gov/globalhealth/

Centers for Disease Control and Prevention
1600 Clifton Rd Atlanta, GA 30329 1-800-CDC-INFO (800-232-4636) TTY: 888-232-6348

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/22/2020 8:55:21 PM
To: Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]
Subject: RE: nCoV portfolio info

Very helpful – thank you

From: Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Sent: Wednesday, January 22, 2020 1:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: nCoV portfolio info

(b)(5)

(b)(5)

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-796-8515
(m) **(b)(6)**
robert.fisher@fda.hhs.gov
U.S. FOOD & DRUG ADMINISTRATION

From: Fisher, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F0CC92E98C4881BD675C3121B343BD-ROBERT.FISH]
Sent: 1/22/2020 10:07:05 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Fwd: starting point for FDA sitrep?

This is what I sent Michael...this is based on the BARDA data I got from him; should have stated that up front....

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza

Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration

(w)301-796-8518
(m (b)(6)
robert.fisher@fda.hhs.gov
robert.fisher@dhs.sgov.gov

From: Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Date: January 22, 2020 at 16:48:00 EST
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: starting point for FDA sitrep?

(b)(5)

(b)(5)

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
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robert.fisher@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/23/2020 11:15:06 AM
To: Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Greetings!

Thank you!

Denise

From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:11 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Greetings!

HI Denise:

I am delighted to hear that you are already on top of this!

-rl

(b)(6)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:07 AM
To: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Greetings!

Good morning, Randy and welcome Dr. Shah. I look forward to meeting with you after you get settled and briefing you about the Office of the Chief Scientist (OCS). We want to ensure our goals are aligned with yours and Dr. Hahn's.

Michael Mair is the Director of OCET within OCS. We will be receiving the EUA for the 2019 n-COV in vitro diagnostic from CDC for review and signature. I informed Dr. Hahn and Keagan of this last night and will keep you in the loop as well.

Best,

Denise

From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Sent: Thursday, January 23, 2020 10:46 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Greetings!

Hi Denise:

I would like to introduce you to Anand Shah, newly arrived Deputy Commissioner for Medical and Scientific Affairs, although you may already know him through other venues. I am sure you will have many topics to discuss, but perhaps a pressing one, which
I mentioned to Anand this morning, involves EUAs, which I believe your office
manages. (See https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization .)

Are you currently developing an EUA for the test that CDC is reportedly using to diagnose the new coronavirus from Wuhan?

If not, is that something that we should be doing?

Carmen Maher's email address is now invalid, presumably because she left the agency, but I do not know who has replaced her as head of CET.

Best regards,

-Randy

Randall Lutter, Ph.D.
Senior Science and Regulatory Advisor
Office of the Commissioner
U.S. Food and Drug Administration

Randall.Lutter@fda.hhs.gov
Cell: (b)(6)
Executive Assistant: Jakea Copeland | Jakea.Copeland@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/23/2020 11:26:40 AM
To: Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]
Subject: RE: Greetings!

I appreciate the email. Please let me know if there is any particular information Anand would like to know in advance of meeting.

Thanks,

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From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:16 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Greetings!

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-rl

(b)(6)

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To: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
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Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
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Michael Mair is the Director of OCET within OCS. We will be receiving the EUA for the 2019 n-COV in vitro diagnostic from CDC for review and signature. I informed Dr. Hahn and Keagan of this last night and will keep you in the loop as well.

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Cel **(b)(6)**

Executive Assistant: Jakea Copeland | Jakea.C●peland@fda.hhs.g●v

U.S. FOOD & DRUG
ADMINISTRATION

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Sent: 1/23/2020 11:30:59 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: Greetings!

Of course!

For now he is doing only meet and greet meetings.

(b)(5)

-rl

(b)(6)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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To: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
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Sent: 1/23/2020 12:47:16 PM
To: Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Fwd: CDC wants FDA to evaluate emergency use for new Wuhan virus test

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From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: January 23, 2020 at 12:45:57 PM EST
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: CDC wants FDA to evaluate emergency use for new Wuhan virus test
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-924728035-1376319-199959@politicoemail.com>

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By David Lim

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The CDC test works by directly detecting the viral genome in an actively or recently infected individual, said Christopher Mores, an arbovirologist and professor of global health at the George Washington University Milken Institute School of Public Health.

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The World Health Organization said Tuesday it is working on a research and development blueprint to speed the development of diagnostic tests and is coordinating global work among researchers and other experts.

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“All of the people who originate in Wuhan and travel into the United States ... will be rerouted into these five,” Cetron said.

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/23/2020 12:51:55 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: CDC wants FDA to evaluate emergency use for new Wuhan virus test

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, January 23, 2020 12:47 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Subject: CDC wants FDA to evaluate emergency use for new Wuhan virus test
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241 HTML-924728035-1376319-199959@politicoemail.com>

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USA .

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Sent: 1/23/2020 1:04:58 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
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Sent: Thursday, January 23, 2020 12:52 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: FW: CDC wants FDA to evaluate emergency use for new Wuhan virus test

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POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA.

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Sent: 1/23/2020 1:09:44 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
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Arlington, VA 22209
USA .

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/23/2020 1:10:00 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: CDC wants FDA to evaluate emergency use for new Wuhan virus test

---

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Thursday, January 23, 2020 1:09 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC wants FDA to evaluate emergency use for new Wuhan virus test

It did. Megan is in the piece responding. And she ran it through proper channels.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, January 23, 2020 12:47 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241 HTML-924728035-1376319-199959@politicoemail.com>

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Sent: 1/23/2020 1:30:05 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
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(b)(5)

If you need any additional information or points of contact, just let us know. Liz is on travel but will be available this afternoon and tomorrow.

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Importance: High

Update please

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To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
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From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 1/23/2020 1:38:15 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Re: CDC wants FDA to evaluate emergency use for new Wuhan virus test

Thanks.

Sent from my iPhone

On Jan 23, 2020, at 1:09 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Yes CDRH is working w/CDC – last I heard is that CDC is anticipating submitting a full data pack for CDRH to review later this week or early next week at the latest. We'll keep you posted.

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To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Sent: 1/23/2020 3:21:54 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Question re: CDC wants FDA to evaluate emergency use for new Wuhan virus test

Thanks – Michael got back to me. Much appreciated - Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Thursday, January 23, 2020 1:30 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
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From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 1/23/2020 4:05:50 PM
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Subject: RE: 2019-nCoV Outbreak FDA SITREP - 23 JAN
Attachments: 01_2019-nCoV Outbreak_FDA SITREP_23 January 2019 oplia.docx

Thanks so much, Michael.

I like the format, but we'll see what Dr. Hahn says.

See two additional items I added under the interagency/intl header.

WE can push to 3:45, but the challenge is that I'll need some window to review before I have to get this to the front office by 4:30 for the Commissioner.

Thanks so much. I know everyone is working hard on this front. Much appreciated, as always!

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 23, 2020 3:33 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: 2019-nCoV Outbreak FDA SITREP - 23 JAN

Anna / Denise,

Hi. Attached is 2019-nCoV Outbreak FDA SITREP - 23 JAN.

Let me know if additional info / edits needed. Feedback on level of info/format would be appreciated.

We would appreciate consideration of a 4 PM deadline as opposed to 3 PM to provide opportunity to capture more updated info and for folks to have more time to provide info…as u can imagine all of the folks involved in response crazy busy.

Thx.

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/23/2020 4:17:39 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: 2019-nCoV Outbreak FDA SITREP - 23 JAN
Attachments: 01_2019-nCoV Outbreak_FDA SITREP_23 January 2019 oplia.docx

Hi – see attached for some further suggestions thx

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, January 23, 2020 4:06 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: 2019-nCoV Outbreak FDA SITREP - 23 JAN

Thanks so much, Michael.

I like the format, but we'll see what Dr. Hahn says.

See two additional items I added under the interagency/intl header.

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To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: 2019-nCoV Outbreak FDA SITREP - 23 JAN

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Let me know if additional info / edits needed. Feedback on level of info/format would be appreciated.

We would appreciate consideration of a 4 PM deadline as opposed to 3 PM to provide opportunity to capture more updated info and for folks to have more time to provide info…as u can imagine all of the folks involved in response crazy busy.

Thx.

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Sent: 1/23/2020 4:24:25 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: 2019-nCoV Outbreak FDA SITREP - 23 JAN
Attachments: 01_2019-nCoV Outbreak_FDA SITREP_23 January 2019 430 pm.docx

Great edits. Here's the final I'm sending up now. THANK YOU!

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, January 23, 2020 4:18 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Sent: 1/24/2020 11:02:48 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: Draft tweets for review RE: COV Tweet

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From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 24, 2020 10:58 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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(b)(5)

(b)(5)

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/24/2020 11:03:00 AM
To: Falvey, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b39be7f55ff242b3a410a30d5ddb1ec7-Mary.Falvey]
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Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 1/24/2020 11:16:14 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: Int Meeting - Denise Hinton / Anand Shah (Introduction)

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Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Greetings!

Thank you!

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202 308 0104

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Cel (b)(6)
Executive Assistant: Jakea Copeland | Jakea.Copeland@fda.hhs.gov

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To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: draft SITREP on the FDA response to the 2019-nCoV outbreak
Attachments: 02_2019-nCoV Outbreak_FDA SITREP_24 January 2019.docx

FYI

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 24, 2020 4:06 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: draft SITREP on the FDA response to the 2019-nCoV outbreak

Emily, thanks for quickly scrubbing the attached update for ethics so we can get to Dr Hahn this afternoon/evening.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: January 24, 2020 at 3:24:07 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: draft SITREP on the FDA response to the 2019-nCoV outbreak

See attached. Thx - m

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Sent: 1/24/2020 4:32:47 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
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Have a great weekend.

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To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: READ NOW

Schedule in two weeks – not urgent for next week – I need to be ready

---

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Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>
Subject: RE: Int Meeting - Denise Hinton / Anand Shah (Introduction)

I'm looking forward to it, Anand. I've copied Mayo and she will work with Jakea to schedule time for us to meet.

Have a great weekend.

Denise

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, January 24, 2020 11:16 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Int Meeting - Denise Hinton / Anand Shah (Introduction)

Randy – Thanks for the kind introduction. Moving to bcc…

Denise – It's so nice to connect. I appreciate your note. Let's find time together, at your convenience. Jakea Copeland has my schedule

Anand

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, January 23, 2020 11:15 AM
To: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Greetings!

Thank you!

Denise

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HI Denise:

I am delighted to hear that you are already on top of this!

-rl

(b)(6)

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Subject: RE: Greetings!

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Michael Mair is the Director of OCET within OCS. We will be receiving the EUA for the 2019 n-COV in vitro diagnostic from CDC for review and signature. I informed Dr. Hahn and Keagan of this last night and will keep you in the loop as well.

Best,

Denise

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I mentioned to Anand this morning, involves EUAs, which I believe your office
manages. (See https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization .)

Are you currently developing an EUA for the test that CDC is reportedly using to diagnose the new coronavirus from Wuhan?

If not, is that something that we should be doing?

Carmen Maher's email address is now invalid, presumably because she left the agency, but I do not know who has replaced her as head of CET.

Best regards,

-Randy

Randall Lutter, Ph.D.
Senior Science and Regulatory Advisor
Office of the Commissioner
U.S. Food and Drug Administration

Randall.Lutter@fda.hhs.gov
Cell **(b)(6)**
Executive Assistant: Jakea Copeland | Jakea.Copeland@fda.hhs.gov

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 1/24/2020 5:14:54 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Meyer, Lyndsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00176f0991c84d34b3927bfb410d5483-Lyndsay.Mey]; Rabin, Tara G. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6e14c0d07ad46ca812a39a72c751bfe-Tara.Goodin]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: RE: FOR YOUR REVIEW - COV Tweets and GRAPHIC FOR TODAY - RE: COV Tweet

Great!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Date: January 24, 2020 at 5:07:19 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Stark, Angela <Angela.Stark@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>, Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: FOR YOUR REVIEW - COV Tweets and GRAPHIC FOR TODAY - RE: COV Tweet

Hi all – wanted to follow up and let you know that OCC has cleared these tweets and the graphic without edits. We plan to share with ASPA for awareness in 15 minutes. Please let us know if you would like us to hold or if you have any comments. Thank you!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: McSeveney, Megan
Sent: Friday, January 24, 2020 4:18 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FOR YOUR REVIEW - COV Tweets and GRAPHIC FOR TODAY - RE: COV Tweet

Hi all- below are the tweets with the edits from Anna incorporated and a graphic that OCET has drafted attached. If the group is comfortable with the attached graphic and the tweets below. We will share with ASPA for awareness and then work on getting these posted. Thank you!

(b)(5)

TWEET 3 of THREAD As with any emerging public health concern, @US_FDA will collaborate with our interagency partners, product developers & intl partners to help expedite development & availability of tools needed to diagnose, treat, mitigate, & prevent outbreaks.

Megan McSeveney
Press Officer

Office of Media Affairs
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Tel: 240-402-4514/Cel (b)(6)
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FDA U.S. FOOD & DRUG ADMINISTRATION

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, January 24, 2020 11:03 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: Draft tweets for review RE: COV Tweet

Thanks

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 24, 2020 10:58 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: Draft tweets for review RE: COV Tweet

I think we need to say something and tweets are probably most appropriate given our role right now. See edits below in highlight.

If Commissioner tweets I'll ask our intl handle to retweet what he puts out.

Thanks!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, January 24, 2020 10:50 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: Draft tweets for review RE: COV Tweet

Hi all – I have drafted tweets below for consideration that we can roll out ASAP if this group and the Commissioner support that. DRAFT THREAD BELOW for consideration.

(b)(5)

(b)(5)

TWEET 3 of THREAD As with any emerging public health concern, @US_FDA will collaborate with our interagency partners, product developers & intl partners to help expedite development & availability of tools needed to diagnose, treat, mitigate, & prevent (b)(5) outbreaks.

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Sent: 1/24/2020 5:22:08 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: READ NOW

I had already sent her times… when she first sent the request.

- Mayo

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, January 24, 2020 4:56 PM
To: Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>
Subject: READ NOW

Schedule in two weeks – not urgent for next week – I need to be ready

---

From: Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>
Sent: Friday, January 24, 2020 4:38 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Int Meeting - Denise Hinton / Anand Shah (Introduction)

I'm already working on this one. ☺

- Mayo

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Sent: Friday, January 24, 2020 4:33 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
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Sent: 1/26/2020 11:09:55 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Info for Coronavirus Briefing with S1

Thanks, very helpful.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, January 26, 2020 10:26 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: RE: Info for Coronavirus Briefing with S1

Thanks Michael.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Sunday, January 26, 2020 10:02 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: Info for Coronavirus Briefing with S1

Hi. Below is some info for tomorrow's briefing. FYI, some of this is confidential - we can share CCI/ TS within HHS – but I am not sure if anyone from outside of HHS is no these calls – and u may want to let folks know that info is confidential.

- On 26 Jan (@ 1:30 AM) FDA authorized an EIND for Remdesivir for the treatment of a patient in the US diagnosed with 2019-nCoV. CDC consulted and Gilead Sciences agreed to supply drug.

- On 26 Jan, FDA received, through the HHS SOC, a request from Gilead related to export of its antiviral product. Working with FDA/OGC, FDA sent instructions on the information needed to comply with export provisions for a sudden and immediate national emergency.
  - Gilead will be providing a statement explaining why it is not feasible to comply with specific regulatory requirements and a letter of request with specified information from a Chinese authorized official.
  - Based on this information, the Secretary will need to make a determination that export may proceed.
  - This Secretarial determination can be sent informally (e.g., through email in response to the request).
  - FDA does not have timing for when this letter of request will arrive.

- CDRH continues to work with CDC on the development of a molecular diagnostic for 2019 -nCoV.
  - FDA anticipates potentially issuing the EUA at the end of this week.
  - FDA continues to (b)(5)

(b)(5) The determination/declaration should continue to be held until we are closer to being ready to issue the EUA.

From: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Sent: 1/27/2020 2:10:16 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]

Subject: Bi-weekly 1:1 Meeting with Hinton/Welch
Attachments: OCS WSR Template v2.docx; Untitled Attachment; Untitled Attachment; Bi-weekly 1:1 Meeting with Hinton/Welch; Untitled Attachment
Location: WO 1, room 3317

Start: 2/3/2020 1:30:00 PM
End: 2/3/2020 2:00:00 PM
Show Time As: Busy

Recurrence: Weekly
every 2 week(s) on Monday from 1:30 PM to 2:00 PM
Required Attendees: Welch, Alice

Please provide your status report no later than noon of one business day prior to your scheduled meeting. Capture as succinctly as possible the highlights of the latest work week(s). Please use brief bulleted list that provide only the most essential and noteworthy information from your activities. Status updates should generally never be longer than a single page. This report will be part of your 1:1 discussion with RADM Hinton.

As discussed in Office Director's meeting, please note the new attached template.

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Sent: 1/27/2020 2:10:16 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]

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To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/27/2020 4:10:31 PM
To: Hinton, Denise (Denise.Hinton@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=HINTOND]
Subject: 03_2019-nCoV Outbreak_FDA SITREP_27 January 2019.docx
Attachments: 03_2019-nCoV Outbreak_FDA SITREP_27 January 2019.docx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/27/2020 4:10:31 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: 03_2019-nCoV Outbreak_FDA SITREP_27 January 2019.docx
Attachments: 03_2019-nCoV Outbreak_FDA SITREP_27 January 2019.docx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/27/2020 4:11:47 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: 27 Jan SITREP
Attachments: 03_2019-nCoV Outbreak_FDA SITREP_27 January 2019.docx

Thanks Michael.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, January 27, 2020 3:56 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: 27 Jan SITREP

Hi – attached is today's draft SITREP. - m

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/28/2020 9:10:29 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Daily updates
Attachments: 03_2019-nCoV Outbreak_FDA SITREP_27 January 2019.docx

Confused - thought you were going to send? Will you be doing so from today forward?

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: January 28, 2020 at 8:52:22 AM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Solomon, Steven M <Steven.Solomon@fda.hhs.gov>, Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>, Mayne, Susan <Susan.Mayne@fda.hhs.gov>, Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Sigg, Jim <Jim.Sigg@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>, Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: COV Update 1/27

We thought it might be helpful to see the daily updates for the Commissioner regarding the COV outbreak. A big thank you to OCET for their work on the outbreak, including compiling the attached.

Yesterday's update is attached. If you or your teams have inputs to help inform, please send to Michael Mair, copied on this note.

Please note that much of this information is very sensitive, close hold, internal as identified in the attached.

Thanks,
Anna

Internal confidential

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/28/2020 5:23:07 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: sitrep
Attachments: 04_2019-nCoV Outbreak_FDA SITREP_28 January 2019.docx

Sorry!

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 1/28/2020 7:01:15 PM
To: Ferro, Phil J. EOP/NSC (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Grogan, Joseph (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6) mie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); 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.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); mize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6); Frater, Eric M (b)(6); Christ, Katelyn E. EOP/NSC (b)(6); Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Gastfriend, Daniel Z. EOP/OMB (b)(6); Landrum, Ryan P. EOP/NSC (b)(6); Rault, Nick M. EOP/NSC (b)(6); Hanna, Cory M. EOP/NSC (b)(6); Burton,

Nicholas S. EOP/OMB [(b)(6)]; Garufi, Marc A. EOP/OMB [(b)(6)]; Mroz, Sara K. EOP/NSC [(b)(6)]; Wade, Dave S. EOP/NSC [(b)(6)]; Troye, Olivia EOP/NSC [(b)(6)]; Carlson, Eric J [(b)(6)]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J. EOP/NSC [(b)(6)]; Cartin, Josh M. EOP/NSC [(b)(6)]; Kanapathy, Ivan J. EOP/NSC [(b)(6)]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian J. EOP/NSC [(b)(6)]; Bakewell, Richard A [(b)(6)]; Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J. EOP/NSC [(b)(6)]; Brett Armstrong - D1R [brett.armstrong@gsa.gov]; paul.detitta@gsa.gov; Marwaha, Brianne C [(b)(6)]; Carstens, Virgil W [(b)(6)]; Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D. EOP/WHO [(b)(6)]; Telle, Adam R. EOP/WHO [(b)(6)]; Sugarman, AJ J. EOP/WHO [(b)(6)]; Planning, David M. EOP/WHO [(b)(6)]; Daravi, Kamran S. EOP/WHO [(b)(6)]; Grewe, Brenda L. EOP/NSC [(b)(6)]; eddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G [(b)(6)]; Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov) [rgreene@usaid.gov]; Baehr, James S. EOP/WHO [(b)(6)]; Magrino, Christopher [(b)(6)]; debbie.w.seguin [(b)(6)]; william.ferrara [(b)(6)]; Deere, Judd P. EOP/WHO [(b)(6)]; Ditto, Jessica E. EOP/WHO [(b)(6)]; Tobin, Elizabeth D. EOP/NSC [(b)(6)]; Jonas, Seth H. EOP/NSC [(b)(6)]; Martin, Gregory J [(b)(6)]; Music, Chris G. EOP/OMB [(b)(6)]; Ali, Nausher [(b)(6)]; Yanick, Brittany M. EOP/WHO [(b)(6)]; Burris, Meghan K. EOP/WHO [(b)(6)]; Henning, Alexa A. EOP/WHO [(b)(6)]; Daravi, Roma S. EOP/WHO [(b)(6)]; Horstman, John H. EOP/WHO [(b)(6)]; MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA) [(b)(6)]; Thallam, Satya P. EOP/OMB [(b)(6)]; Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; alexandra.doumas@usdoj.gov

CC: Wilson, John Mark M. EOP/NSC [(b)(6)]; Martin, Michael E. EOP/NSC [(b)(6)]; donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC [(b)(6)]; Gray, Alexander B. EOP/NSC [(b)(6)]; Rubini, Jeffrey H. EOP/NSC [(b)(6)]; Stahlman, James E CIV OSD OUSD POLICY (USA) [(b)(6)]; Ullyot, Jonathan L. EOP/NSC [(b)(6)]; Stufft, Julie M. EOP/NSC [(b)(6)]; Doster, Kim M. EOP/OSTP [(b)(6)]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Hayes, Bradley F. EOP/OMB [(b)(6)]; Browne, Lisa Y. EOP/NSC [(b)(6)]; Davis, May M. [(b)(6)]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B. EOP/NSC [(b)(6)]; Smith, Gregory L. EOP/WHO [(b)(6)]; Bailey, Drew M. EOP/OMB [(b)(6)]; Allen, Ronald G. EOP/NSC [(b)(6)]; Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Bain, Ally P. EOP/OMB [(b)(6)]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA) [(b)(6)]

Subject: Canceled: Canceled: EOP and Interagency nCoV Daily Synch Meeting

Attachments: UPDATE nCoV Restricted (b)(5) *Please read message below**; Canceled: EOP and Interagency nCoV Daily Synch Meeting
Location: WHSR and SVTC

Start: 1/27/2020 11:00:00 AM
End: 1/27/2020 12:20:00 PM
Show Time As: Free

Importance: High

Dear Colleagues,

Please accept this invite to attend a daily sitrep and synch meeting. (b)(5) (b)(5) The meeting will take place in the WHSR. Due to limited space we welcome D/A to attend in person, but have also set up participation via SVTC.

Please use the WAVES link below for in person attendance.

(b)(6)

Thank you,

Phil and Lauren

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 1/28/2020 7:01:15 PM
To: Ferro, Phil J. EOP/NSC (b)(6) Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Baum, Kristina R. EOP/OSTP (b)(6) Bicket, Mark C. EOP/OSTP (b)(6) Blair, Robert (b)(6) Bonyun, Sean C. EOP/OSTP (b)(6) Butterfield, Nicholas W. EOP/WHO (b)(6) Campana, Alexandra D. EOP/WHO (b)(6) DL NSC Defense (b)(6) DL NSC Legal (b)(6) DL NSC NSA FO Staff (b)(6) DL NSC STRATCOM (b)(6) Grogan, Joseph (b)(6) Hudson, Renee R. EOP/WHO (b)(6) Jack, Brian T. EOP/WHO (b)(6) Kan, Derek T. EOP/OMB (b)(6) Kratsios, Michael J. EOP/OSTP (b)(6) Lattimore, Tracie B. EOP/OSTP (b)(6) Lin, Merry S. EOP/WHO (b)(6) McKenna, Michael A. EOP/WHO (b)(6) Merkel, Theo W. EOP/WHO (b)(6) Miles, Aaron R. EOP/OSTP (b)(6) Olmem, Andrew J. (b)(6) Pataki, Tim A. EOP/WHO (b)(6) Ray, Paul J. EOP/OMB (b)(6) Wong, Anna W. EOP/CEA (b)(6) Walters, William (b)(6) Bonner, Maria K. EOP/WHO (b)(6) Droegemeier, Kelvin K. EOP/OSTP (b)(6) Sinclair, Michael R. EOP/NSC (b)(6) DL NSC WMD (b)(6) Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6) amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6) ; Limage, Julia (b)(6) Seffel, Gary A. EOP/NSC (b)(6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6) ; Waterman, Elijah J. EOP/NSC (b)(6) Watson, Ian D. EOP/OSTP (b)(6) ; Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6) 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.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6) ; Scovitch, Joseph R (b)(6) Costello, Kelly E (b)(6) DL NSC (b)(6) ; DL NSC Asia (b)(6) ; DL NSC Press (b)(6) DL NSC Resilience (b)(6) ; DL NSC HSA FO Staff (b)(6) DL NSC Legislative (b)(6) DL NSC BATS (b)(6) Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6) Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6) ; Gulati, Neetu (b)(6) Liebschutz, Jennifer E. EOP/OMB (b)(6) Farquharson, Christine E. EOP/OMB (b)(6) mize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6) Tully, Ryan M. EOP/NSC (b)(6) ; Frater, Eric M (b)(6) ; Christ, Katelyn E. EOP/NSC (b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Gastfriend, Daniel Z. EOP/OMB (b)(6) Landrum, Ryan P. EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M. EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi, Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Wade, Dave S. EOP/NSC (b)(6) Troye, Olivia EOP/NSC (b)(6) Carlson, Eric J (b)(6) ; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J. EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) ; Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J. EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov]; paul.detitta@gsa.gov; Marwaha, Brianne C (b)(6) ; Carstens, Virgil W (b)(6) Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D. EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) ; Sugarman, AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6) Daravi, Kamran S. EOP/WHO (b)(6) Grewe, Brenda L. EOP/NSC (b)(6) ; Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov) [rgreene@usaid.gov]; Baehr, James S. EOP/WHO (b)(6) Magrino, Christopher (b)(6) debbie.w.seguin (b)(6) ; william.ferrar (b)(6) Deere, Judd P. EOP/WHO (b)(6) Ditto, Jessica E. EOP/WHO (b)(6) Tobin, Elizabeth D. EOP/NSC (b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J (b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6) Yanick, Brittany M. EOP/WHO (b)(6) Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO (b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA) (b)(6)

Subject: EOP and Interagency nCoV Daily Synch Meeting
Attachments: UPDATE nCoV Restricted (b)(5) *Please read message below**
Location: WHSR and SVTC

Start: 1/27/2020 11:00:00 AM
End: 1/27/2020 12:20:00 PM
Show Time As: Tentative

-----Original Appointment-----
From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: Sunday, January 26, 2020 6:05 PM
To: Ferro, Phil J. EOP/NSC; Baum, Kristina R. EOP/OSTP; Bicket, Mark C. EOP/OSTP; Blair, Robert; Bonyun, Sean C. EOP/OSTP; Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; DL NSC Defense; DL NSC Legal; DL NSC NSA FO Staff; DL NSC STRATCOM; Grogan, Joseph; Hudson, Renee R. EOP/WHO; Jack, Brian T. EOP/WHO; Kan, Derek T. EOP/OMB; Kratsios, Michael J. EOP/OSTP; Lattimore, Tracie B. EOP/OSTP; Lin, Merry S. EOP/WHO; McKenna,

Michael A. EOP/WHO; Merkel, Theo W. EOP/WHO; Miles, Aaron R. EOP/OSTP; Olmem, Andrew J. EOP/WHO; Pataki, Tim A. EOP/WHO; Ray, Paul J. EOP/OMB; Wong, Anna W. EOP/CEA; Walters, William; Bonner, Maria K. EOP/WHO; Droegemeier, Kelvin K. EOP/OSTP; Sinclair, Michael R. EOP/NSC; DL NSC WMD; Cetron, Martin (CDC); gary.c.rasicot (b)(6) amie.kalsbeek (b)(6) Naar, Alex (FAA); Firoved, Aaron; Limage, Julia; Seffel, Gary A. EOP/NSC; Redfield, Robert R (CDC); Waterman, Paige E. EOP/OSTP; Waterman, Elijah J. EOP/NSC; Watson, Ian D. EOP/OSTP; Biles, Amber D CDR USN OSD OUSD POLICY (USA); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); Marks, Peter; Mair, Michael; Kadlec, Robert P (OS); Kerr, Lawrence (OS); Grigsby, Garrett G (OS); Disbrow, Gary (OS); Tobert, Gwen M; Scovitch, Joseph R; Costello, Kelly E; DL NSC IO; DL NSC Asia; DL NSC Press; DL NSC Resilience; DL NSC HSA FO Staff; DL NSC Legislative; DL NSC BATS; Redd, John T (OS); Cornett, Elizabeth A CIV (USA); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA); Gulati, Neetu; Liebschutz, Jennifer E. EOP/OMB; Farquharson, Christine E. EOP/OMB; lmize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden; Boney, Virginia M. EOP/WHO; Tully, Ryan M. EOP/NSC; Frater, Eric M; Christ, Katelyn E. EOP/NSC; Weinberger, Collin (OS); Gastfriend, Daniel Z. EOP/OMB; Landrum, Ryan P. EOP/NSC; Rault, Nick M. EOP/NSC; Hanna, Cory M. EOP/NSC; Burton, Nicholas S. EOP/OMB; Garufi, Marc A. EOP/OMB; Mroz, Sara K. EOP/NSC; Wade, Dave S. EOP/NSC; Troye, Olivia EOP/NSC; Carlson, Eric J; McGowan, Robert K (CDC); Lowry, Patrick J. EOP/NSC; Cartin, Josh M. EOP/NSC; Kanapathy, Ivan J. EOP/NSC; Elvander, Erika (OS); Cavanaugh, Brian J. EOP/NSC; Bakewell, Richard A; Thomas, Gloria D (OS); Butler, Jay C (CDC); Bright, Rick (OS); Ruggiero, Anthony J. EOP/NSC; Brett Armstrong - D1R; paul.detitta@gsa.gov; Marwaha, Brianne C; Carstens, Virgil W; Hassell, David (OS); McMillin, Virginia D. EOP/WHO; Telle, Adam R. EOP/WHO; Sugarman, AJ J. EOP/WHO; Planning, David M. EOP/WHO; Daravi, Kamran S. EOP/WHO; Grewe, Brenda L. EOP/NSC; Feddersen, Brett (FAA); Padget, Larry G; Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov); Baehr, James S. EOP/WHO; Magrino, Christopher; debbie.w.seguin (b)(6) william.ferrara (b)(6) ; Deere, Judd P. EOP/WHO; Ditto, Jessica E. EOP/WHO; Tobin, Elizabeth D. EOP/NSC; Jonas, Seth H. EOP/NSC; Martin, Gregory J; Music, Chris G. EOP/OMB; Ali, Nausher; Yanick, Brittany M. EOP/WHO; Burris, Meghan K. EOP/WHO; Henning, Alexa A. EOP/WHO; Daravi, Roma S. EOP/WHO; Horstman, John H. EOP/WHO; MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)

Subject: EOP and Interagency nCoV Daily Synch Meeting

When: Occurs every day effective 1/27/2020 until 2/8/2020 from 11:00 AM to 12:20 PM Eastern Standard Time.

Where: WHSR and SVTC

Dear Colleagues,

Please accept this invite to attend a daily sitrep and synch meeting. (b)(5) The meeting will take place in the WHSR. Due to limited space we welcome D/A to attend in person, but have also set up participation via SVTC.

Please use the WAVES link below for in person attendance.

(b)(5)

Thank you,

Phil and Lauren

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/28/2020 8:02:09 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: FW: Instructions for nCoV (b)(5) omorrow
Attachments: nCoV_(b)(5) Agenda_29Jan.docx

FYI

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: Tuesday, January 28, 2020 7:36 PM
Subject: Instructions for nCoV (b)(5) omorrow

Dear Colleagues,

(b)(5)

Please use the WAVES link to register for attendance. (b)(6)

Invited Attendees:

- OVP
- NEC
- DPC
- White House CoS

- White House Legal
- OMB
- NSC- Legal, BATS, Resilience, Stratcom, Legislative
- State
- HHS
- HHS/ASPR
- HHS/CDC
- HHS/NIAID
- DoJ
- DoT
- FAA
- DHS
- DHS/CBP

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Coun cil
202.456.1222 (O (b)(6)
(b)(6)

Sent: 1/28/2020 8:06:33 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: nCoV Update 1/28
Attachments: 04_2019-nCoV Outbreak_FDA SITREP_28 January 2019.docx

Good evening,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn each evening.

As Anna noted yesterday, please be discerning when disseminating further to your staff as much of this information is very sensitive, close hold, internal as identified in the attached document.

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service

Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/28/2020 9:04:53 PM
To: Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]
Subject: FYSA: nCoV Update 1/28
Attachments: 04_2019-nCoV Outbreak_FDA SITREP_28 January 2019.docx

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From: Hinton, Denise
Sent: Tuesday, January 28, 2020 9:04 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: nCoV Update 1/28

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If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn each evening.

(b)(5)

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal confidential

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 1/28/2020 10:06:36 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Fwd: Can you send me the WSJ piece
Attachments: Act Now to Prevent an American Epidemic - WSJ.pdf

---

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Date: January 28, 2020 at 9:15:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: Can you send me the WSJ piece

Hi – the text is copied below and I've tried to attach a PDF. Here is the link too.

The novel coronavirus now epidemic in China has features that may make it very difficult to control. If public-health authorities don't interrupt the spread soon, the virus could infect many thousands more around the globe, disrupt air travel, overwhelm health-care systems, and, worst of all, claim more lives. The good news: There's still an opening to prevent a grim outcome.

China failed to contain the virus early. More cases in the U.S. are inevitable. Experience with the 2009 H1N1 flu pandemic suggests that emergency measures such as school closures and border screening—in place at 20 U.S. airports—can at most buy time. Several traits of the virus make border surveillance less effective. It results in a respiratory illness that looks like many other diseases. Some infected people won't show symptoms while they're traveling. Checkpoints don't have tests that can diagnose the virus rapidly.

The U.S. government's actions to prevent the virus from entering the country are valuable, and there aren't many good options in such early stages of crisis response. But it's time for additional measures. As more U.S. cases develop, the strategy needs to incorporate another goal: preventing transmission of the coronavirus within the U.S. Four important steps now could help.

First, the most important public-health tool for containment is the identification and isolation of cases to break the chain of spread. Public-health authorities and health-care systems are on high alert for potential cases. But authorities can't act quickly without a test that can diagnose the condition rapidly.

Health-care providers are relying on a polymerase chain reaction, or PCR, test conducted only at the Centers for Disease Control and Prevention. This test can be very accurate. But the procedure currently requires sending patient samples out to the CDC. It takes at least a couple of days to receive test results. Meanwhile, patients must be kept in isolation.

If the number of cases increases, experience from the 2009 swine flu pandemic and the 2015 Zika epidemic suggests that the CDC will struggle to keep up with the volume of screening. Government should focus on working with private industry to develop easy-to-use, rapid diagnostic tests that can be made available to providers.

Second, focus on the flu. The incidence of flu and other respiratory viral infection cases is high right now in the U.S. It isn't too late to boost flu vaccination efforts, which would reduce the burden that influenza puts on doctors and hospitals. It could also reduce the number of patients showing up at the emergency room with a respiratory illness that requires testing to rule out the novel coronavirus.

Third, hospitals need to prepare for an influx of patients who will need to be isolated. It isn't well understood how this virus is transmitted. There are reports of hospital staff in China coming down with the virus despite wearing protective gowns and masks.

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Press Officer

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U.S. Food and Drug Administration
Tel: 240-402-4514 (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 9:09 PM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: Can you send me the WSJ piece

Lu Borio and dr. Gottlieb put out on coronavirus? Thanks.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/28/2020 10:20:44 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Can you send me the WSJ piece

Thanks

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:07 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Fwd: Can you send me the WSJ piece

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Date: January 28, 2020 at 9:15:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: Can you send me the WSJ piece

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The novel coronavirus now epidemic in China has features that may make it very difficult to control. If public-health authorities don't interrupt the spread soon, the virus could infect many thousands more around the globe, disrupt air travel, overwhelm health-care systems, and, worst of all, claim more lives. The good news: There's still an opening to prevent a grim outcome.

China failed to contain the virus early. More cases in the U.S. are inevitable. Experience with the 2009 H1N1 flu pandemic suggests that emergency measures such as school closures and border screening—in place at 20 U.S. airports—can at most buy time. Several traits of the virus make border surveillance less effective. It results in a respiratory illness that looks like many other diseases. Some infected people won't show symptoms while they're traveling. Checkpoints don't have tests that can diagnose the virus rapidly.

The U.S. government's actions to prevent the virus from entering the country are valuable, and there aren't many good options in such early stages of crisis response. But it's time for additional measures. As more U.S. cases develop, the strategy needs to incorporate another goal: preventing transmission of the coronavirus within the U.S. Four important steps now could help.

First, the most important public-health tool for containment is the identification and isolation of cases to break the chain of spread. Public-health authorities and health-care systems are on high alert for potential cases. But authorities can't act quickly without a test that can diagnose the condition rapidly.

Health-care providers are relying on a polymerase chain reaction, or PCR, test conducted only at the Centers for Disease Control and Prevention. This test can be very accurate. But the procedure currently requires sending patient samples out to the CDC. It takes at least a couple of days to receive test results. Meanwhile, patients must be kept in isolation.

If the number of cases increases, experience from the 2009 swine flu pandemic and the 2015 Zika epidemic suggests that the CDC will struggle to keep up with the volume of screening. Government should focus on working with private industry to develop easy-to-use, rapid diagnostic tests that can be made available to providers.

Second, focus on the flu. The incidence of flu and other respiratory viral infection cases is high right now in the U.S. It isn't too late to boost flu vaccination efforts, which would reduce the burden that influenza puts on doctors and hospitals. It could also reduce the number of patients showing up at the emergency room with a respiratory illness that requires testing to rule out the novel coronavirus.

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Press Officer

Office of Media Affairs
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Tel: 240-402-451[redacted] (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 9:09 PM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: Can you send me the WSJ piece

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/28/2020 10:36:11 PM
To: Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]
Subject: WSJ
Attachments: Act Now to Prevent an American Epidemic - WSJ.pdf

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/28/2020 10:52:29 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Comms

I'm going to bed – see you tomorrow. Thanks for everything!

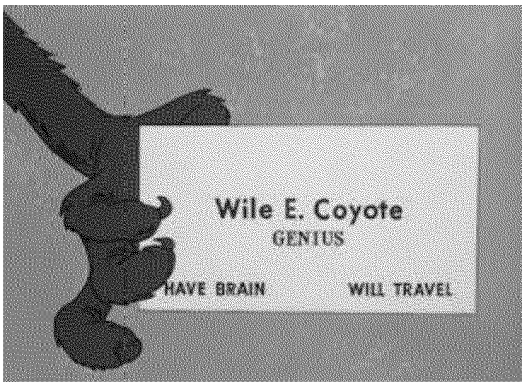
From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:47 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Comms

The 9 AM is on tomorrow – the 11 AM is off

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:43 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Comms

I needed a good laugh! The Phil meeting still shows on my calendar for 0900 – ignore? Also, I sent a note to Laura – hopefully, she's getting more sleep than we are.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:41 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Comms



From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:35 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Comms

I'm trying to showcase your brilliance, dude!

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:28 PM

To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Comms

Ha – u meant Anna and DH

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:25 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Comms

You and Dr. Hahn should do the same – go for it!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 10:07 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Fwd: Can you send me the WSJ piece

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Date: January 28, 2020 at 9:15:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
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Press Officer

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U.S. Food and Drug Administration
Tel: 240-402-4514 **(b)(6)**
Megan.McSeveney@fda.hhs.gov

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Sent: Tuesday, January 28, 2020 9:09 PM
To: Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: Can you send me the WSJ piece

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From: Chukwudebe, Nnaemeka [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=510E95FD635344B89E21E3D249D57046-NNAEMEKA.CH]
Sent: 1/29/2020 1:02:23 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: Urgent: For FDA Review: 2019 nCOV EUD Package
Attachments: 012420208002 Determination of PHE- Coronaviruses ASPR to Sec DM Clean execsec 1-27-2020.docx; 012420208002 Determination of PHE- Coronaviruses SPPR to ASPR Clean execsec 1-27-2020.docx; EUA FR notice 2019-nCoV FINAL.docx; Senate Ltr EUA 2019-nCoV FINAL.docx; House Ltr EUA 2019-nCoV FINAL.docx; EUA declaration - 2019 nCoV_FINAL.doc

Importance: High

Hello,

We just received the attached Request from the Department to review the 2019 nCOV EUD Package. The Department has requested that FDA review and clear the package by 12:00 PM on January 30, 2020. Please see attached documents. In addition, below are two emails from the Department explaining the documents. Given the subject matter, can the Office of Chief Scientist (OCS) and Office of Counterterrorism and Threat (OCET) please review? Please let me know at your earliest convenience. Please also respond if you don't have a response or think the package should get redirected. Please respond by **9:00 AM Thursday January 30, 2020**. Thank you.

Sincerely,

Emeka Chukwudebe
Policy Analyst
Office of the Commissioner
Office of the Executive Secretariat
U.S. Food and Drug Administration
Tel: (301) 796-7873
nnaemeka.chukwudebe@fda.hhs.gov

From: ASPR-SPPR-ExecSec (OS/ASPR) <ASPR-SPPR-ExecSec@hhs.gov>
Sent: Wednesday, January 29, 2020 12:50 PM
To: ASPR-SPPR-ExecSec (OS/ASPR) <ASPR-SPPR-ExecSec@hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Cc: Hrdina, Chad (OS) <Chad.Hrdina@hhs.gov>; Ezernack, Paige (OS) <Paige.Ezernack@hhs.gov>
Subject: RE: For FDA Review: 2019 nCOV EUD Package

Dear Colleagues,

(b)(5)

Very Respectfully,

Chad

Chad M. Hrdina, MS, GC-WMD, EMT, notary public
Director, Division of Requirements
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements

HEALTH AND HUMAN SERVICES | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
(202) 205-3510
www.phe.gov | REMM | CHEMM

From: ASPR-SPPR-ExecSec (OS/ASPR) <ASPR-SPPR-ExecSec@hhs.gov>
Sent: Wednesday, January 29, 2020 12:18 PM
To: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Cc: ASPR-SPPR-ExecSec (OS/ASPR) <ASPR-SPPR-ExecSec@hhs.gov>; Hrdina, Chad (OS) <Chad.Hrdina@hhs.gov>; Ezernack, Paige (OS) <Paige.Ezernack@hhs.gov>
Subject: For FDA Review: 2019 nCOV EUD Package

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(b)(5)

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(202) 205-3510
www.phe.gov | REMM | CHEMM

From: Petersen, Lyle (CDC/DDID/NCEZID/DVBD) [lxp2@cdc.gov]
Sent: 1/29/2020 2:07:06 PM
To: Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Mac Kenzie, William R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c613b964123b415c96769628d2da6d27-HHS-wrm0-cd]; Erbelding, Emily J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c981f04015d64d27b1afdd9c06111071-HHS-emily.e]; Abbey, Lillian T (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6a5145b237d549fb83024d8c39d001e4-HHS-LABBEY-]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Fine, Joshua B. [Joshua.Fine@tunnellgov.com]; Overman, Lauren R. [Lauren.Overman@tunnellgov.com]; Petersen, Lyle R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86e045ba633049f9827fe7c77bce1c67-HHS-lxp2-cd]; Beard, Charles B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=658d55d71e2641aba3ffb0699a6aef14-HHS-cbb0-cd]
Subject: RE: Point-of-care diagnostic testing
Attachments: ciy614.pdf; cix943.pdf

Tammy,

Currently, there is one 1st tier point of care serologic test FDA cleared for Lyme (Sofia 2 Lyme FIA, Quidel). http://www.quidel.com/immunoassays/rapid-lyme-tests/sofia-2-lyme-fia. This test requires a special instrument (Sofia 2) that scans the test strip, analyzes the fluorescent signal, and displays two (2) test results for IgM and IgG. It has limited utility as point of care at this time as requires the special instrument as well as a second-tier immunoblot if the test is positive. CDC has supplied samples from the Lyme serum repository to another manufacturer who is also working on development of a 1st tier point of care for Lyme. Like the Quidel lateral flow, this test is only intended as 1st tier and will display two test results, one for IgM and one for IgG. We are not aware of any manufacturers developing a stand-alone point of care serologic assay for Lyme as we have not received any requests for samples from Lyme serum repository specifically for this purpose.

There are several considerations for a stand-alone point of care diagnostic test:

- Serology is very insensitive in early Lyme disease, which accounts for the vast majority of cases. It is unlikely that a point-of-care test would have a higher sensitivity than current laboratory-based tests.
- In terms of clinical use, a stand-alone point of care serology might be more useful for those patients suspected of Lyme neuroborreliosis, Lyme carditis or Lyme arthritis, because a detectable antibody response would be expected and diagnosis is more difficult for these manifestations based on clinical features. In these cases, particularly for carditis or neuroborreliosis, we would recommend initial treatment upon clinical suspicion, so I'm not sure a point-of-care test would be very useful. And again, these are a small percentage of all Lyme patients.
- The other problem with point-of-care tests in general is that they depend on a visual interpretation of the result and may be over-read. We know there is a lot of inappropriate testing for Lyme disease, such as for people who have not lived or traveled to locations where there is no Lyme disease or for symptoms unlikely due to Lyme. Therefore, having a test with a very high specificity is critically important since the pre-test probability is low. Thus, with a rapid test that depends on visual interpretations of results, there is huge potential for many false-positive test interpretations.
- Direct detection tests are an option, but so far they lack sensitivity. To my knowledge, none have been developed as a point-of-care test.

As background, I've attached two manuscripts. The Clinical Infectious Disease paper is a little out of date in that FDA has approved a two-EIA approach instead of EIA and Western blot (this change is already reflected in the slide deck).

Let me know if you need additional information.

Lyle

Lyle R. Petersen, MD, MPH
Director
Division of Vector-Borne Diseases
Centers for Disease Control and Prevention
3156 Rampart Road
Fort Collins, CO 80521
Phone: 970-221-6428
Email: LXP2@CDC.GOV

From: Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>
Sent: Wednesday, January 29, 2020 8:39 AM
To: Mac Kenzie, William R. (CDC/DDPHSS/CSELS/OD) <wrm0@cdc.gov>; Erbelding, Emily (NIH/NIAID) [E] <emily.erbelding@nih.gov>; Abbey, Lillian (NIH/NIAID) [E] <LABBEY@niaid.nih.gov>; Petersen, Lyle (CDC/DDID/NCEZID/DVBD) <lxp2@cdc.gov>; Hinton, Denise (FDA/OC) <Denise.Hinton@fda.hhs.gov>
Cc: Fine, Joshua B. <Joshua.Fine@tunnellgov.com>; Overman, Lauren R. <Lauren.Overman@tunnellgov.com>
Subject: Point-of-care diagnostic testing

Good morning everyone one thing I wanted to point out in preparation for the briefing for the **(b)(5)** **(b)(5)**

If you have additional information other than what we seen in the PowerPoint please send that---- and NIH am still waiting for your slides, we'd like to put the slide deck together today as he will probably want it definitely late this week so he can start reviewing it.

Dr. Beckham

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/29/2020 4:25:18 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: 29 Jan SITREP
Attachments: 05_2019-nCoV Outbreak_FDA SITREP_29 January 2019.docx

thx

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/29/2020 6:44:53 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
CC: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]
Subject: RE: Coronavirus briefing draft memo
Attachments: 20200130 Hinton-EnC Memo (6)_MM.docx

Hi – sorry to be late to this – **(b)(5)** ..see attached. Don't know if too late.

(b)(5)

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Wednesday, January 29, 2020 6:08 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Cc: Gross, Karas <Karas.Gross@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Coronavirus briefing draft memo

Dear all,

Thank you Denise and everyone for meeting at the last minute to prep for tomorrow's briefing. Attached is the draft coronavirus memo, please note that it is being agency cleared now (via SP link). We'll send the final version asap, but we just wanted to get it in front of you now. Fyi, the talking points have been pulled from our website and other cleared documents, and the QA will probably require the most review.

Here is the readout we received from today's full House briefing.

(b)(5)

Regarding a funding question, OCA cleared the info in the memo, but HHS just confirmed that CDC or ASPR will be able to address that if it comes up. Please let us know if we can provide additional information.

Thank you,

Prakash

Sent: 1/29/2020 7:16:03 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: FDA nCoV Update 1/29
Attachments: 05_2019-nCoV Outbreak_FDA SITREP_29 January 2019.docx

Good evening,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn each evening.

Please be discerning when disseminating further to your staff as much of this information is very sensitive, close hold, internal as identified in the attached document.

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal, confidential

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 1/30/2020 9:01:32 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
Subject: Re: Coronavirus briefing prep
Attachments: 20200130 Hinton-EnC Memo 013020.docx

I'm about 10 min away. Attached is the final OCC cleared version.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: January 30, 2020 at 8:53:03 AM EST
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Subject: Re: Coronavirus briefing prep

I just arrived and am in the very back of the cafeteria.

Thanks,

Denise

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
When: January 30, 2020 at 9:15:00 AM EST
Required: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: Coronavirus briefing prep
Location: Rayburn cafeteria - basement floor

Hi all,

If you're able to, please meet in the Rayburn cafeteria tomorrow morning at 9:15 to go over any last second intel. If you need anything in the meanwhile, please feel free to email, call, text me at **(b)(6)**

Thanks,
Prakash

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 1/30/2020 12:02:37 PM
To: DL NSC Defense (b)(6); DL NSC Lega (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OST (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); lmize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6); Frater, Eric M (b)(6); Christ, Katelyn E. EOP/NSC

(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d8996760309189 73af8-HHS-Collin.]; Landrum, Ryan P. EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M. EOP/NSC (b)(6); Burton, Nicholas S. EOP/OMB (b)(6); Garufi, Marc A. EOP/OMB (b)(6); Mroz, Sara K. EOP/NSC (b)(6); Wade, Dave S. EOP/NSC (b)(6); Troye, Olivia EOP/NSC (b)(6) Carlson, Eric J (b)(6); McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J. EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan J. EOP/NSC (b)(6); Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian J. EOP/NSC (b)(6); Bakewell, Richard A (b)(6); Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J. EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov]; paul.detitta@gsa.gov; Marwaha, Brianne C (b)(6) Carstens, Virgil W (b)(6) Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D. EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Sugarman, AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6) Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov) [rgreene@usaid.gov]; Baehr, James S. EOP/WHO (b)(6) Magrino, Christopher (b)(6) debbie.w.seguin (b)(6) william.ferrara (b)(6) Tobin, Elizabeth D. EOP/NSC (b)(6); Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J (b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6) Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO (b)(6) Daravi, Roma S. EOP/WHO (b)(6); Horstman, John H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA) (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Martin, Michael E. EOP/NSC (b)(6)]; donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC (b)(6) Gray, Alexander B. EOP/NSC (b)(6); Rubini, Jeffrey H. EOP/NSC (b)(6) Stahlman, James E CIV OSD OUSD POLICY (USA) (b)(6) Ullyot, Jonathan L. EOP/NSC (b)(6) Stufft, Julie M. EOP/NSC (b)(6) Doster, Kim M. EOP/OSTP (b)(6); Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC (b)(6); Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B. EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Bain, Ally P. EOP/OMB (b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D. EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA) (b)(6)

CC: Havranek, John (b)(6) Dumm, Christopher M (b)(6) FORET, VERNON T (b)(6) Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]
Subject: nCoV Daily (b)(5) Agenda for January 31, 2020
Attachments: nCoV (b)(5) _Agenda_Jan31.docx

Dear Colleagues,

Please find attached and below the detailed agenda for the meeting tomorrow.

(b)(5)

Best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (O) (b)(6)
Philip.J.Ferro (b)(6)

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/30/2020 4:21:57 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: 30 Jan SITREP
Attachments: 06_2019-nCoV Outbreak_FDA SITREP_30 January 2019.docx

Sent: 1/30/2020 7:30:14 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: FDA nCoV Update 1/30
Attachments: 06_2019-nCoV Outbreak_FDA SITREP_30 January 2019.docx

Dear colleagues,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn each evening.

Please be discerning when disseminating further to your staff as much of this information is very sensitive, close hold, internal as identified in the attached document.

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal, confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/30/2020 10:47:52 PM
To: Raza, Mark [Mark.Raza@fda.hhs.gov]
Subject: FW: FDA nCoV Update 1/30
Attachments: 06_2019-nCoV Outbreak_FDA SITREP_30 January 2019.docx

My apologies – I will add you to the list.

Best,

Denise

From: Hinton, Denise
Sent: Thursday, January 30, 2020 7:30 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FDA nCoV Update 1/30

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Internal, confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/30/2020 10:53:48 PM
To: Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]
Subject: FW: FDA nCoV Update 1/30
Attachments: 06_2019-nCoV Outbreak_FDA SITREP_30 January 2019.docx

I will include you – thank you.

From: Hinton, Denise
Sent: Thursday, January 30, 2020 7:30 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FDA nCoV Update 1/30

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Internal, confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 1/31/2020 12:06:42 PM
To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: Fwd: Scheduling: Coronavirus Medical Countermeasures Emergency Use Authorization Briefing

This is urgent

From: Price, William <William.Price@fda.hhs.gov>
Date: January 31, 2020 at 12:03:21 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Singh, Patrice <Patrice.Singh@fda.hhs.gov>, Jackson, Cheyenne <Cheyenne.Jackson@fda.hhs.gov>, Vega, Jacqueline <Jacqueline.Vega@fda.hhs.gov>
Cc: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>, Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>
Subject: Scheduling: Coronavirus Medical Countermeasures Emergency Use Authorization Briefing

Hi all,

OCA received a phone briefing request this morning from House Majority staff on coronavirus and FDA's emergency use authorization. We also expect Budget questions related to Coronavirus response to come up during this briefing. House Majority staff have requested that this briefing occur sometime early next week.

In order to schedule this phone briefing, **by 2PM today**, please provide periods of availability on **Tuesday, February 4th** and **Wednesday, February 5th** for Denise Hinton, Anna Abram and Bill Tootle. In addition, please also provide periods of availability on **Monday, February 3rd** in order to schedule a 30 minute pre-briefing prep meeting. Please reply all to this chain.

Apologies for the short turnaround, as we have been given a quick timeframe with this briefing request.

Please let me know if you have any questions.

Thanks,

Taylor Price

Taylor Price
Office of Congressional Appropriations
U.S. Food and Drug Administration
William.Price@fda.hhs.gov

From: Vega, Jacqueline [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=84DFCBB07CBB4B219EAB9DEBDCDDD7DE-JACQUELINE.]
Sent: 1/31/2020 12:54:19 PM
To: Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Singh, Patrice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f541d08e079464ba70929944bb73b30-Patrice.Sin]; Jackson, Cheyenne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=800a3f896c2c44a0a39e0a0cfc51a0d2-Cheyenne.Ja]
CC: Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]
Subject: RE: Scheduling: Coronavirus Medical Countermeasures Emergency Use Authorization Briefing

Bill Tootle's availability:
2/3: 1:30-5 pm
2/4: 3-5 pm
2/5: 11-Noon, 2-3 pm, 4-5 pm

V/R,

Jacquie Vega
Executive Assistant to William A. Tootle, Director | Office of Budget | OB and
Eric Wong, Deputy Director | Office of Budget | OB
Food and Drug Administration
4041 Powder Mill Road, 72087A
Beltsville, MD 20705
O +240.402.4713 | Jacqueline.Vega@ fda.hhs.gov

OFFICE OF FINANCE BUDGET
AND ACQUISITIONS
#OFBAWhereTheStewardshipHappens

From: Price, William <William.Price@fda.hhs.gov>
Sent: Friday, January 31, 2020 12:03 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Singh, Patrice <Patrice.Singh@fda.hhs.gov>; Jackson, Cheyenne <Cheyenne.Jackson@fda.hhs.gov>; Vega, Jacqueline <Jacqueline.Vega@fda.hhs.gov>
Cc: Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>
Subject: Scheduling: Coronavirus Medical Countermeasures Emergency Use Authorization Briefing

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availability on **Monday, February 3rd** in order to schedule a 30 minute pre-briefing prep meeting. Please reply all to this chain.

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Please let me know if you have any questions.

Thanks,

Taylor Price

_ _ _

Taylor Price
Office of Congressional Appropriations
U.S. Food and Drug Administration
William.Price@fda.hhs.gov

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 1/31/2020 1:10:17 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
CC: Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]
Subject: FW: Hill call adjustment
Attachments: 20200130 Hinton-EnC Memo 013020.docx

Hi Denise,

I'll be joining you in your office, and will come by at 1:40. Please see the run of show below, FDA is being asked to respond to QA only. Attached is the same QA doc from yesterday's briefing, which we will use today. The only update we received is the pre-EUA number.

- To assist diagnostic developers, we have developed an Emergency Use Authorization review template for tests to detect the novel coronavirus, which outlines the data requirements for a Pre-EUA package, which is available to developers upon request…and have already sent it to ~~fourteen~~ nineteen diagnostic developers.

See you soon,
Prakash

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Friday, January 31, 2020 12:32 PM
To: Berkson, Laura D (NIH) <laura.berkson@nih.gov>
Cc: Brand, Anstice M (CDC) <atb6@cdc.gov>; Oxner, Julie (OS) <Julie.Oxner@hhs.gov>; Tourk, Nancy R (CDC) <wxk8@cdc.gov>; Bigham, Jane E (CDC) <vsy0@cdc.gov>; Serna, Christina (CDC) <yyh9@cdc.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tatem, Anne (OS) <Anne.Tatem@hhs.gov>; Shuy, Caitrin (OS) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (OS) <Alexander.Pinson@hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; LaMontagne, Karen A (NIH) <karen.lamontagne@nih.gov>
Subject: RE: Hill call adjustment

Updated script. You can send any updates to the old script though if you had already started working on it. I'm going to send this script to the interagency group in 10 minutes unless I hear from folks. Thanks!!

(b)(5)

(b)(5)

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Friday, January 31, 2020 12:15 PM
To: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Cc: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>; Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; LaMontagne, Karen (NIH/OD) [E] <karen.lamontagne@nih.gov>
Subject: Re: Hill call adjustment

Whoops! Thank you! Reading too quickly on my phone.

Sent from my iPhone

On Jan 31, 2020, at 12:14 PM, Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov> wrote:

(b)(5)

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Friday, January 31, 2020 12:12 PM
To: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Cc: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>; Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; LaMontagne, Karen (NIH/OD) [E] <karen.lamontagne@nih.gov>
Subject: Re: Hill call adjustment

Thanks, Laura! So only HHS speakers for this call?

Sent from my iPhone

On Jan 31, 2020, at 12:08 PM, Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov> wrote:

Yes they will. Please see below for a draft script for me to moderate the call. Please edit!!

(b)(5)

(b)(5)

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Friday, January 31, 2020 12:00 PM
To: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>
Cc: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; LaMontagne, Karen (NIH/OD) [E] <karen.lamontagne@nih.gov>
Subject: RE: Hill call adjustment

Got it. Thanks, Anstice! That's really helpful. So will the hill notifications going out at 12:30 and 12:45 also tell Hill staff about the 1:45 call?

From: Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>
Sent: Friday, January 31, 2020 11:52 AM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>; Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Tourk, Nancy R. (CDC/OD/CDCWO) <WXK8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>
Cc: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; LaMontagne, Karen (NIH/OD) [E] <karen.lamontagne@nih.gov>
Subject: RE: Hill call adjustment

Hi Laura, the 1pm is a media call CDC is doing, so no need for a speaker on that. We will be sending a listen only line with a request that people be sparing with the number of lines they use. The 1:45pm is the interagency hill briefing.

From: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>
Sent: Friday, January 31, 2020 11:39 AM
To: Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>
Cc: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; LaMontagne, Karen (NIH/OD) [E] <karen.lamontagne@nih.gov>
Subject: RE: Hill call adjustment

Hi Laura,

Thanks for the update! So just to clarify, a NIAID speaker is only needed for the 1:45 call? Not the 1:00 call?

Can you explain the difference between the 1pm and 1:45pm calls?

Thanks,
Laura

From: Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>
Sent: Friday, January 31, 2020 11:31 AM
To: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@CDC.GOV>; Tourk, Nancy R. (CDC/OD/CDCWO) <WXK8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>
Cc: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Subject: RE: Hill call adjustment

(b)(5)

Thanks,
Julie

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Friday, January 31, 2020 11:28 AM
To: Berkson, Laura (NIH/OD) [E] <laura.berkson@nih.gov>; Brand, Anstice M. (CDC/OD/CDCWO) <atb6@cdc.gov>; Tourk, Nancy R. (CDC/OD/CDCWO) <wxk8@cdc.gov>; Bigham, Jane E. (CDC/OD/CDCWO) <vsy0@cdc.gov>; Serna, Christina (CDC/OD/CDCWO) <yyh9@cdc.gov>; Oxner, Julie (OS/ASPR/OEA) <Julie.Oxner@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>
Cc: Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Subject: Hill call adjustment

Hi All,

Because of additional announcements coming out today, our Hill calls have changed slightly. Please see adjusted times below:

(b)(5)

Let me know if you have any questions, and thanks for your flexibility. (b)(6)

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 1/31/2020 4:21:26 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

I was also thinking of **(b)(5)** Great suggestion.

Michael, do you want to check with Peter, Janet, and Jeff and then pass back a suggested list for FDA?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, January 31, 2020 4:20 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, January 31, 2020 4:18 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

(b)(5) Will look for and suggest others.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: January 31, 2020 at 4:12:01 PM EST
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

Any suggested names?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, January 31, 2020 3:42 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

I think it is great.

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 31, 2020 1:56 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

Laura, in case you have thoughts from a stakeholder outreach perspective

Thanks!

Internal confidential

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Friday, January 31, 2020 1:47 PM
To: Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Handley, Gray G (NIH) <handleygr@niaid.nih.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Fox, LeAnne M (CDC) <lff4@cdc.gov>; Greene, Carolyn M (CDC) <cgg4@cdc.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; OGA-Wuhan-nCoV <OGA-Wuhan-nCoV@hhs.gov>
Subject: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

During the Secretary's nCoV briefing yesterday, **(b)(5)**

(b)(5)

Thank you for considering this request,

Larry

Larry

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 1/31/2020 4:21:57 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

(b)(5)

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, January 31, 2020 4:21 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

Oh yeah and **(b)(5)**

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, January 31, 2020 4:18 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

(b)(5) Will look for and suggest others.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: January 31, 2020 at 4:12:01 PM EST
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

Any suggested names?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, January 31, 2020 3:42 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

I think it is great.

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

[redacted]

[redacted]

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 31, 2020 1:56 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

Laura, in case you have thoughts from a stakeholder outreach perspective

Thanks!

Internal confidential

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Friday, January 31, 2020 1:47 PM
To: Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Handley, Gray G (NIH) <handleygr@niaid.nih.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Jernigan, Daniel B (CDC) <dbj0@cdc.gov>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Fox, LeAnne M (CDC) <lff4@cdc.gov>; Greene, Carolyn M (CDC) <cgg4@cdc.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Cc: Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; OGA-Wuhan-nCoV <OGA-Wuhan-nCoV@hhs.gov>
Subject: [Request - NOT Urgent] Secretary's Request for nCoV/Pandemic Preparedness & Response Thought Leaders

During the Secretary's nCoV briefing yesterday, **(b)(5)**

(b)(5)

Thank you for considering this request,

Larry

Larry

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/31/2020 5:32:02 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: todays sitrep
Attachments: 07_2019-nCoV Outbreak_FDA SITREP_31 January 2020.docx

Peter said fine to send w/link so use this version if u have not already sent.

From: Mair, Michael
Sent: Friday, January 31, 2020 5:16 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: todays sitrep
Importance: High

Anna /Denise use this version – **(b)(5)**

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Friday, January 31, 2020 5:13 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: todays sitrep

He has, and I'm all set. This is cleared for ethics to share with Dr. Hahn.

Michael, thanks for checking on SP access. I got an error message just now when I tried. Will we be providing these reports over the weekend, or resume on Monday?

Thanks,
Emily

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 31, 2020 5:08 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: todays sitrep

Michael, please send the latest directly to Emily for review. I'm tied up on other related materials.

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Friday, January 31, 2020 5:08 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: RE: todays sitrep

Thanks! Sorry, I just meant you could share with me (b)(5) I don't have SharePoint access.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, January 31, 2020 5:05 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: RE: todays sitrep

(b)(5)

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Friday, January 31, 2020 5:03 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: RE: todays sitrep

(b)(5)

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, January 31, 2020 4:44 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: todays sitrep

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 1/31/2020 5:41:07 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: OPDIV and Agency links to Coronavirus

Hi – for some reason the link to the FDA page in the document does not work

https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/novel-coronavirus-2019-ncov

we link to additional sources of info from our page…

If your company is developing diagnostics, therapeutics, vaccines, or other products, submit your ideas to BARDA's online portal.

Additional resources

- Coronavirus informationExternal Link Disclaimer from the World Health Organization (WHO)
- Novel Coronavirus Disease Outbreak NewsExternal Link Disclaimer (WHO)
- Interim Guidance for Healthcare Professionals (CDC)
- Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspectedExternal Link Disclaimer (WHO)
- 2019 Novel Coronavirus (Occupational Safety and Health Administration (OSHA), U.S. Department of Labor)
- Novel Coronavirus (2019-nCoV) advice for the publicExternal Link Disclaimer, including how to protect yourself and others from getting sick (WHO)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, January 31, 2020 5:32 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: FW: OPDIV and Agency links to Coronavirus

From: Snyder, Heidi <Heidi.Snyder@fda.hhs.gov>
Sent: Friday, January 31, 2020 2:56 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: OPDIV and Agency links to Coronavirus

Good Afternoon,

(b)(5) Angel requested I do research to see what info other OPDIVS and Agencies have to link to (see attachment). Angel or Tiffany Branch will be in touch to further discuss.

Have a great weekend!

Heidi

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/2/2020 7:21:00 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: Fwd: (b)(4)
Attachments: RE: (b)(4)

Importance: High
Sensitivity: Company Confidential

So you have the accompanying attachment as well

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: February 2, 2020 at 6:45:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd (b)(4)
Importance: High

Hi Anna and Keagan -

(b)(5)

Thanks
Anand

From: Ashley Rhoades (b)(6)
Date: February 2, 2020 at 6:18:33 PM EST
To: Shah, Anand (b)(6)
Cc: Paul Tomkins (b)(6), Diana Brainard (b)(6), Leighann Timbs (b)(6)
Subject: (b)(4)
Importance: High

Dear Dr. Shah:

(b)(4)

Any assistance you can provide, would be appreciated. I can be reached directly at: (b)(6) Alternatively and if needed, you can reach out to Leighann Timbs at (b)(6)

Best,
Ashley Rhoades

Ashley Rhoades, MBS, RAC | Senior Associate, Regulatory Affairs
(650) 425 5190 | (b)(6)
Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404 | United States

From: Ross, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AE562EA1D840A3ACA172D0CC23F368-ROSSJ]
Sent: 2/2/2020 11:03:16 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: MDIC
Attachments: Remarks - Hinton- MDIC 2-3-20.docx; MDIC EUA workshop agenda 2020.02.03 FINAL.pdf

Hi – I had heard Mary Falvey was revising your remarks, but I don't have anything she might have prepared. There was one sentence to delete in what I sent last week.

Final agenda is attached also.

Although the workshop is really about transitioning from EUA to De Novo/510k/PMA and planned far before the novel coronavirus became an issue, you may want to be aware of the article from Gottlieb and Borio calling for rapid diagnostics, and Gottlieb's Twitter (of note, the public health emergency announced by HHS Friday was under section 319 of the PHS Act and not the same declaration that's needed for the EUAs. We have the EUA declaration poised with the Secretary to issue the same day as the CDC EUA.)

https://www.wsj.com/articles/act-now-to-prevent-an-american-epidemic-11580255335
https://mobile.twitter.com/ScottGottliebMD/status/1224042220665307137/photo/1

MedTech Dive did a short article on the workshop.
https://www.medtechdive.com/news/amid-coronavirus-outbreak-fda-and-industry-seek-roadmap-for-emergency-diag/571418/

Thanks,

Jennifer

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, February 02, 2020 8:31 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Subject: MDIC

Hi Jennifer,

Is there any additional information or revisions necessary for remarks tomorrow?

Thanks,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/2/2020 11:05:24 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
Subject: FW: Remarks for Monday speech-MDIC_mbf.docx
Attachments: Remarks - Hinton- MDIC_mbf.docx

Importance: High

Hi Jennifer,

Attached is a copy for your reference.

Thank you,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/3/2020 7:48:49 AM
To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: Fwd: Remarks for Monday speech-MDIC_mbf.docx
Attachments: Remarks - Hinton- MDIC_mbf.docx

This one please

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Date: February 3, 2020 at 6:52:20 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Remarks for Monday speech-MDIC_mbf.docx

Here are a few suggested deletions in tracked changes.

Thanks,

Jennifer

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, February 02, 2020 11:09 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Subject: RE: Remarks for Monday speech-MDIC_mbf.docx

You're welcome. Let me know if I need to scratch anything -it's lengthy. See you in the morning. Thanks!

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Sunday, February 2, 2020 11:07 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Remarks for Monday speech-MDIC_mbf.docx

Thanks!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, February 02, 2020 11:05 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Subject: FW: Remarks for Monday speech-MDIC_mbf.docx
Importance: High

Hi Jennifer,

Attached is a copy for your reference.

Thank you,

Denise

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 2/3/2020 10:34:23 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: (b)(4)
Sensitivity: Company Confidential

Thanks everyone

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 3, 2020 at 10:23:12 AM EST
To: Shah, Anand <Anand.Shah@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: **(b)(4)**

Michael, I'll loop Anand in when I speak with Dr. Hahn in follow up so no need to back brief him. I know you are 24/7 on CoV front right now. Thanks, all!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 3, 2020 8:54 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: (b)(4)
Sensitivity: Confidential

Good morning Michael –

(b)(5)

Thanks,
Anand

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Sunday, February 2, 2020 7:21 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>
Subject: RE: (b)(4)
Sensitivity: Confidential

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Sunday, February 2, 2020 6:59 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Re: (b)(4)
Sensitivity: Confidential

(b)(5)

Internal confidential

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Date: February 2, 2020 at 6:45:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: Fwd: (b)(4)
Importance: High

Hi Anna and Keagan -

(b)(5)

Thanks
Anand

From: Ashley Rhoades (b)(6)
Date: February 2, 2020 at 6:18:33 PM EST
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Paul Tomkins (b)(6), Diana Brainard (b)(6), Leighann Timbs (b)(6)
Subject: (b)(4)
Importance: High

Dear Dr. Shah:

(b)(4)

Any assistance you can provide, would be appreciated. I can be reached directly at: (b)(6) Alternatively and if needed, you can reach out to Leighann Timbs at (b)(6)

Best,
Ashley Rhoades

Ashley Rhoades, MBS, RAC | Senior Associate, Regulatory Affairs
(650) 425 5190 | (b)(6)
Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404 | United States

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/3/2020 12:05:12 PM
To: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]
Subject: (b)(5)

Close hold

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: February 3, 2020 at 11:49:00 AM EST
To: Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Marks, Peter <Peter.Marks@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>, Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>, Kibunja, Julia (OS) <Julia.Kibunja@hhs.gov>, LaHood, Natalie (OS) <Natalie.Lahood@hhs.gov>
Subject: Re: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics

Yes. Bob walker.

On Feb 3, 2020, at 11:42 AM, Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov> wrote:

Mike Ryan/Anna Maria just called and requested that HHS draft a (b)(5)

(b)(5)

Much thanks

Larry

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/3/2020 12:42:56 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Barber, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a326d10d4c5483f843dbb9d59bf1e5d-Daniel.Barb]
Subject: RE: For Clearance ASAP today - SMH CoV internal email message
Attachments: nCoV Dear Colleagues_02.03.2020 oplia.docx

One minor edit – this is great – thank you!

Denise

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Monday, February 3, 2020 11:25 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: RE: For Clearance ASAP today - SMH CoV internal email message

Additional edits in track changes.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 3, 2020 10:42 AM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Barber, Daniel

<Daniel.Barber@fda.hhs.gov>
Subject: RE: For Clearance ASAP today - SMH CoV internal email message

My suggested edits in the attached. Please continue to copy me on the email thread as this goes to Dr. Hahn for his review. Thanks, all.

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Monday, February 3, 2020 8:35 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: For Clearance ASAP today - SMH CoV internal email message

Good morning,

Attached for your review and comment is the email update on CoV from Dr. Hahn to all FDA staff. Please provide your edits by 11:30 a.m. today if possible.

Thank you,
Sandy

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/3/2020 1:06:35 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics

Thanks!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, February 3, 2020 1:03 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Re: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics

Yes - sent to John and Debbie for review

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 3, 2020 at 1:01:57 PM EST
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics
Importance: High

Confirming you are routing to our CDER colleagues in follow up – thanks, Michael.

Internal confidential

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, February 3, 2020 11:43 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Kibunja, Julia (OS) <Julia.Kibunja@hhs.gov>; LaHood, Natalie (OS) <Natalie.Lahood@hhs.gov>
Subject: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics
Importance: High

Mike Ryan/Anna Maria just called and requested that HHS draft a (b)(5)

(b)(5)

Much thanks

Larry

From: Farley, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D9DC8109C3EA49ED8F897AC979B0619B-FARLEYJ]
Sent: 2/3/2020 3:20:23 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Styrt, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=458d7290e25347c2801b8214b89d81fa-STYRTB]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: For review: **(b)(5)**

Hi Denise:
Based on the call one week ago with WHO on the development of a master protocol, I would be on the larger advisory group and John Biegle and Libby Higgs, very experienced trialists at NIAID, were going to be on the smaller writing group. I have and will provide input to John and Libby from our DAV team re design experience in other situations that might be relevant. That provides distance for us as this will likely come in as an IND.
If this is morphing a bit, I am happy to be the main point of contact and participant for clinical trial development for therapeutics.

John Farley
Office phone: 301-796-4978

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, February 3, 2020 1:39 PM
To: Farley, John <John.Farley@fda.hhs.gov>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Styrt, Barbara <Barbara.Styrt@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: For review: **(b)(5)**

My apologies for duplicative email – resending for awareness, review and input.

Thank you,

Michael and Denise

From: Hinton, Denise
Sent: Monday, February 3, 2020 1:03 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Re: **(b)(5)**

Yes - sent to John and Debbie for review

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 3, 2020 at 1:01:57 PM EST
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: **(b)(5)**
Importance: High

Confirming you are routing to our CDER colleagues in follow up – thanks, Michael.

Internal confidential

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, February 3, 2020 11:43 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Kibunja, Julia (OS) <Julia.Kibunja@hhs.gov>; LaHood, Natalie (OS) <Natalie.Lahood@hhs.gov>
Subject: **(b)(5)**
Importance: High

Mike Ryan/Anna Maria just called and requested that HHS draft a **(b)(5)**

(b)(5)

Is it possible to put together a team that could assist in this clinical trial development? If possible, **(b)(5)**

(b)(5)

Much thanks

Larry

From: Price, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4F6E66E367574338B48ECA70C18EDDA5-WILLIAM.PRI]
Sent: 2/3/2020 3:27:06 PM
To: Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Tootle, William [William.Tootle@fda.hhs.gov]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; McBride, Maren [Maren.McBride@fda.hhs.gov]; Klimczak, Katherine [Katherine.Klimczak@fda.hhs.gov]
CC: Nguyen, Michael A. [Michael.Nguyen1@fda.hhs.gov]

Subject: Prep Meeting re: Briefing with House and Senate Subcommittee Clerks on Medical Countermeasures Emergency Use Authorization re: Coronavirus
Attachments: 2020 0205 EUA Coronavirus Briefing.docx
Location: Room TBD; Conference Line: 1-(877)-465-7975; Attendee Code: **(b)(6)**

Start: 2/4/2020 4:30:00 PM
End: 2/4/2020 5:30:00 PM
Show Time As: Tentative

Required Attendees: Abram, Anna; Anderson, Erika; Tootle, William; Hinton, Denise; McBride, Maren; Klimczak, Katherine

Attaching a briefing memo.

Conference Line: 1-(877)-465-7975; Attendee Code: **(b)(6)**

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/3/2020 5:17:49 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: today's sitrep
Attachments: 08_2019-nCoV Outbreak_FDA SITREP_03 February 2020.docx

Sorry – crazy day

Sent: 2/3/2020 5:43:39 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Solomon, Steven M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e49ac6a056dc4f299ea269945e962e82-SSOLOMON]; Zeller, Mitchell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de7d2fda971e418ba33cb211a4013976-Mitchell.Ze]; Mayne, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e69acd84a37469aa57466a957814563-Susan.Mayne]; Yiannas, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93cdf56a41324683ab173699c441fec8-Frank.Yiann]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
Subject: RE: FDA nCoV Update February 3, 2020
Attachments: 08_2019-nCoV Outbreak_FDA SITREP_03 February 2020.docx

Dear colleagues,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn.

Please be discerning when disseminating further to your staff as much of this information is very sensitive, close hold, internal as identified in the attached document.

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal, confidential

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 2/3/2020 8:11:01 PM
To: Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: 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]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; LaHood, Natalie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef807c1a1b9a4b739bc63954bfb71386-HHS-Natalie]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]
Subject: RE: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics

Thanks for the headsup Larry and Tony. Please include **(b)(5)**

(b)(5)

Thanks, Rick

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, February 03, 2020 5:43 PM
To: Fauci, Anthony (NIH/NIAID) [E] **(b)(6)** ; Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Hinton, Denise (FDA/OC) <Denise.Hinton@fda.hhs.gov>
Cc: Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Kibunja, Julia (OS/OGA) <Julia.Kibunja@hhs.gov>; LaHood, Natalie (OS/OGA) <Natalie.Lahood@hhs.gov>; Lane, Cliff (NIH/NIAID) [E] **(b)(6)**
Subject: RE: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics

Thank you Sir,

I'll connect with **(b)(5)**

(b)(5)

Larry

From: Fauci, Anthony (NIH/NIAID) [E] (b)(6)
Sent: Monday, February 3, 2020 12:32 PM
To: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Hinton, Denise (FDA/OC) <Denise.Hinton@fda.hhs.gov>
Cc: Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Kibunja, Julia (OS/OGA) <Julia.Kibunja@hhs.gov>; LaHood, Natalie (OS/OGA) <Natalie.Lahood@hhs.gov>; Lane, Cliff (NIH/NIAID) [E] (b)(6)
Subject: RE: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics

Larry:
In response to the request from WHO via OGA for the USG to develop an RCT for treatment of nCoV2019 it is important to point out and for you to appreciate the activities that are currently underway that could very likely be leveraged for this purpose.

1. Gilead is already working with Peter Horby, Fred Hayden and Chinese colleagues to develop a treatment RCT. It would be important for any WHO-coordinated effort to be aligned with this effort. (A concern expressed by WHO is that they want a study where they [WHO] control the data.)

2. There is currently a USG working group involved in developing a treatment protocol that could be used internationally. This effort is being led by NIAID's Division of Microbiology and Infectious Diseases (DMID). Dr. John Beigel is the current DMID lead. BARDA has been playing a role in product selection. We can encourage this group to work in conjunction with the WHO and the Horby/Hayden protocol.

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 (b)(6)

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, February 3, 2020 11:43 AM
To: Abram, Anna (FDA/OC) <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b)(6) Marston,

Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Hinton, Denise (FDA/OC) <Denise.Hinton@fda.hhs.gov>
Cc: Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Kibunja, Julia (OS/OGA) <Julia.Kibunja@hhs.gov>; LaHood, Natalie (OS/OGA) <Natalie.Lahood@hhs.gov>
Subject: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics
Importance: High

Mike Ryan/Anna Maria just called and requested that HHS draf (b)(5)

(b)(5)

Much thanks

Larry

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/3/2020 9:41:33 PM
To: Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; 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.]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]
Subject: (b)(5)

Larry – hi – John Farley will be the main point of contact (b)(5) for FDA thx -m

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, February 3, 2020 11:43 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Kibunja, Julia (OS) <Julia.Kibunja@hhs.gov>; LaHood, Natalie (OS) <Natalie.Lahood@hhs.gov>
Subject: [Urgent WHO Request] USG Experts to Draft Clinical Trial Protocol for Investigational Therapeutics
Importance: High

Mike Ryan/Anna Maria just called and requested that HHS draft a (b)(5)

(b)(5)

Much thanks

Larry

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/4/2020 8:10:49 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Gibney, Jaycie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=390bd4f246ee4a97ada93d146d6d7276-Jaycie.Gibn]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: Requesting Expedited and Concurrent Clearance of PR for CDC Diagnostic EUA - 9am deadline
Attachments: CLEANdraft ncov diagnostic eua_PR-2.4.20.docx; draft ncov diagnostic eua_PR-2.4.20.docx

Good morning! **We are requesting expedited clearance of this draft PR by 9am today – apologies – this is moving quickly.** There are clean and track changed versions attached. Please work off the CLEAN VERSION. The track changed version has feedback from OPLIA and Anna and is included for reference. Thank you all so much!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514 **(b)(6)**
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/4/2020 1:47:04 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]
CC: Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
Subject: Flagging: All hands cleared
Attachments: Dear Colleagues.docx

Importance: High

We believe we have checked all the boxes to clear this all hands—including HHS, CDC, NIH.

Anna and Keagan– (b)(5) Thank you.

From: Ross, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AE562EA1D840A3ACA172D0CC23F368-ROSSJ]
Sent: 2/4/2020 3:00:41 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: For signature today: CDC 2019-nCoV EUA Issuance
Attachments: 2-CDC 2019-nCoV Letter of Authorization DRAFT 02042020 FINAL.doc; 3-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel HCP FS 02042020 FINAL.docx; 4-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Patient FS 02042020 FINAL.docx; 5a-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use 02042020.docx; 5b-CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel PIS and VR 02042020.pdf

RADM Hinton,

I'm bringing down a copy for you to sign as attached for signature is the letter to issue an EUA for CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel. The EUA package was cleared by CDRH (U.Scherf), OCC (C.Dennis), and OCET (M. Mair) today.

Documents attached:

- EUA Letter of Authorization
- Fact Sheet for Patients
- Fact Sheet for Healthcare Providers
- Instructions for Use and PIV

(b)(5)

Please let me know if you have any questions.

Thank you,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/4/2020 3:08:54 PM
To: Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]
Subject: FDA nCoV Update February 3, 2020
Attachments: 08_2019-nCoV Outbreak_FDA SITREP_03 February 2020.docx

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From: Hinton, Denise
Sent: Monday, February 3, 2020 5:46 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Zeller, Mitchell <Mitchell.Zeller@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: FDA nCoV Update February 3, 2020

Dear colleagues,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily. Information received will be collated and provided to Dr. Hahn.

(b)(5)

Many thanks to all of you for your support.

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal, confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/4/2020 3:30:28 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: FYI - Signed copy: CDC 2019-nCoV EUA
Attachments: SIGNED_CDC_2019_nCoV_EUA_Ltr.pdf; CDC 2019-nCoV Letter of Authorization 02042020 FINAL.doc; CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel HCP FS 02042020 FINAL.docx; CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel HCP FS 02042020 FINAL.pdf; CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Patient FS 02042020 FINAL.docx; CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Patient FS 02042020 FINAL.pdf; CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel Instructions for Use 02042020.docx; CDC 2019-nCoV Real_Time RT-PCR Diagnostic Panel PIS and VR 02042020.pdf

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From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Tuesday, February 4, 2020 3:28 PM
To: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; McFarland, Scott <Scott.McFarland@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Kesha <Kesha.Hinton@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Spillar, Patricia <Patricia.Spillar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: FYI - Signed copy: CDC 2019-nCoV EUA

Hello,

Please find attached the pdf and Word documents of the EUA package for CDC's 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel

- Letter (Signed pdf and Word)
- Fact Sheet for Healthcare Providers (Word and pdf)
- Fact Sheet for Patients (Word and pdf)
- Instructions for Use (Word only)
- PIS and VR (pdf only)

A hard copy is being sent to CDC via UPS today.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration

Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/4/2020 4:25:37 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: FDA SITREP 04 FEB
Attachments: 09_2019-nCoV Outbreak_FDA SITREP_04 February 2020.docx

thx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/4/2020 4:49:49 PM
To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: 09_2019-nCoV Outbreak_FDA SITREP_04 February 2020.docx
Attachments: 09_2019-nCoV Outbreak_FDA SITREP_04 February 2020.docx

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/5/2020 6:39:50 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: Fwd: Can you send the WSJ piece
Attachments: wsj gottlieb article 020420.docx

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Date: February 4, 2020 at 11:34:59 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: RE: Can you send the WSJ piece

Here you go – also shared an attachment in case the formatting comes out a bit funky. Thank you! Megan

Stop a U.S. Coronavirus Outbreak Before It Starts

It's time to start testing patients with unexplained pneumonia, even if they haven't traveled to China.
By
Luciana Borio and
Scott Gottlieb
Feb. 4, 2020 6:38 pm ET

Travelers wearing medical masks at the airport in Los Angeles, Feb. 2. PHOTO: DAVID MCNEW/GETTY IMAGES

The Wuhan coronavirus continues to spread at an alarming rate. More than 20,000 cases have been confirmed in China, with another 23,000 suspected. Many in China aren't even being tested due to a shortage of diagnostic supplies. The true number infected is likely much higher than reported. The virus has turned up in 28 other countries, including the U.S. A pandemic seems inevitable.

The U.S. government has moved quickly to try to delay the spread throughout America. As of Feb. 2, most foreign nationals who have traveled in China in the preceding 14 days aren't able to enter the country. Americans and their immediate family who recently traveled to China are subject to medical screening and quarantine.

These travel measures may stall a U.S. outbreak. But they'll become less effective as more cases appear outside China. It's clear that China waited several weeks to tell the world about the outbreak. Meanwhile, roughly 250,000 Chinese nationals traveled to the U.S. People with only mild symptoms can spread the virus to close contacts.

So far the 11 known U.S. cases are recent travelers to Wuhan and their household contacts. But it's highly probable that dozens of other cases have gone undetected. The first sign of an outbreak will be a cluster of patients in one community stricken with unexplained pneumonia. The priority should be identifying this community transmission early, so that public-health authorities can intervene and prevent spread throughout the U.S. That will require several steps.

First, doctors must be on high alert. The Centers for Disease Control and Prevention should expand its guidance to doctors: Be suspicious of anyone with unexplained pneumonia who tests negative for common viruses, even if the patient has no connection to China.

An expanded sentinel surveillance system—detailed data collected from a network of high-risk locations—could help spot unusual clusters of illness that might be the beginning of an outbreak. If only 10% to 20% of people develop serious symptoms, then for every person diagnosed there may be eight or nine who elude detection.

Second, these expanded criteria should translate into broader screening. It's crucial to identify cases of secondary spread, in which someone catches the virus from another person who hasn't recently been to China.

CDC currently recommends testing only those with a clear and known risk factor, such as travel to China or close contact with an infected or exposed person. The patient must also be showing symptoms, such as fever and shortness of breath. This strategy will miss illnesses coming from a potential outbreak in which the index case—the person who traveled to China, for example—is two or three steps removed from the people who show up at the hospital with pneumonia. It's time to start testing more people, even if they haven't visited China or been in contact with someone infected.

Containing the virus will also require more labs that can perform diagnostic tests. Right now only the CDC is running tests, and the agency is showing signs of strain. It's taking CDC about 36 hours to turn around results, even with strict limitations on who should be tested. Expanded screening will further stretch the agency.

CDC is planning to distribute test kits as soon as this week that would allow designated public-health labs to run the test. Private test developers need clearance from the Food and Drug Administration to distribute or use tests. But that will take some time. Developers need access to samples to be sure their tests are reliable, and companies have to submit paperwork for FDA review.

Many major medical centers in the U.S. already have the capacity to run tests. The test is based on polymerase chain reaction, or PCR, that screens for bits of the coronavirus RNA. Most major hospitals have sophisticated labs that can conduct these tests. This type of test is relatively cheap, technically straightforward and routinely used by doctors. CDC can help by giving hospitals more access to positive controls and reference material.

If the virus is silently spreading among people without a connection to China, and if only a fraction of the ill develop pneumonia, then it might take dozens of infections to notice an outbreak. By that time, an epidemic will be hard to prevent.

Dr. Borio is a vice president at In-Q-Tel and was director for medical and biodefense preparedness policy at the National Security Council, 2017-19. Dr. Gottlieb is a resident fellow at the American Enterprise Institute and a board member of health-care companies. He was commissioner of the Food and Drug Administration, 2017-19.

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, February 04, 2020 9:23 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: Can you send the WSJ piece

On coronavirus? Looks like Lu Borio and Gottlieb co-authored

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/5/2020 9:25:15 AM
To: Fabina, Lauren C. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nich olasW. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); 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.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); lmize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6); Frater, Eric M (b)(6); Christ, Katelyn E. EOP/NSC

(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P. EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M. EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi, Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Wade, Dave S. EOP/NSC (b)(6) Troye, Olivia EOP/NSC (b)(6) ; Carlson, Eric J (b)(6) McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J. EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian J. EOP/NSC (b)(6) ; Bakewell, Richard A (b)(6) Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J. EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov]; paul.detitta@gsa.gov; Marwaha, Brianne C (b)(6) Carstens, Virgil W (b)(6) Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D. EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) ; Sugarman, AJ J. EOP/WHO (b)(6) ; Planning, David M. EOP/WHO (b)(6) Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov) [rgreene@usaid.gov]; Baehr, James S. EOP/WHO (b)(6) ; Magrino, Christopher (b)(6) ; debbie.w seguin (b)(6) william.ferrara (b)(6) ; Tobin, Elizabeth D. EOP/NSC (b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J (b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6) Burris, Meghan K. EOP/WHO (b)(6) ; Henning, Alexa A. EOP/WHO (b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA) (b)(6) Wilson, John Mark M. EOP/NSC (b)(6) Martin, Michael E. EOP/NSC (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC (b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H. EOP/NSC (b)(6) Stahlman, James E CIV OSD OUSD POLICY (USA) (b)(6) Ullyot, John L. EOP/NSC (b)(6) Stufft, Julie M. EOP/NSC (b)(6) Doster, Kim M. EOP/OSTP (b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC (b)(6) Davis, May M. EOP/WHO (b)(6) ekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B. EOP/NSC (b)(6) ; Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya P. EOP/OMB (b)(6) ; Allen, Ronald G. EOP/NSC (b)(6) Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Bain, Ally P. EOP/OMB (b)(6) ; Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDI BOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D. EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office (b)(6) Ash, Deborah J. EOP/NSC (b)(6) ; Decker, Matthew G. EOP/NSC (b)(6) Carter, Hillary H. EOP/NSC (b)(6) ; Reilly, Tom

M. EOP/OMB (b)(6) ; Havranek, John (b)(6) Dumm, Christopher M (b)(6) ; FORET, VERNON T (b)(6) Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; JACKSTA, LINDA L (b)(6) Parra, Yolanda A (b)(6) ; Galkowski, James J. EOP/WHO (b)(6) Tokumasu de Silva, Miriam E (b)(6)

Subject: 5 February Novel Coronavirus (b)(5) *Agenda***

Attachments: nCoV Feb (b)(5) Agenda_FINAL.docx

Colleagues,

Please find attached the agenda for the (b)(5) hat will take place this afternoon.

Classification of this meeting will be at (b)(5)

Best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
202.456.1222 (O) (b)(6) **(cell)**
(b)(6)

-----Original Appointment-----
From: Fabina, Lauren C. EOP/NSC (b)(6)
Sent: Tuesday, February 4, 2020 8:22 AM
To: Fabina, Lauren C. EOP/NSC; DL NSC Defense; DL NSC Legal; DL NSC NSA FO Staff; DL NSC STRATCOM; Droegemeier, Kelvin K. EOP/OSTP; Daravi, Kamran S. EOP/WHO; Grewe, Brenda L. EOP/NSC; Deere, Judd P. EOP/WHO; Ditto, Jessica E. EOP/WHO; Yanick, Brittany M. EOP/WHO; Hayes, Bradley F. EOP/OMB; Smith, Gregory L. EOP/WHO; Cetron, Marty (CDC/DDID/NCEZID/DGMQ); Gastfriend, Daniel Z. EOP/OMB; Baum, Kristina R. EOP/OSTP; Bicket, Mark C. EOP/OSTP; Blair, Robert B. EOP/WHO; Bonyun, Sean C. EOP/OSTP; Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; Grogan, Joseph J. EOP/WHO; Hudson, Renee R. EOP/WHO; Jack, Brian T. EOP/WHO; Kan, Derek T. EOP/OMB; Kratsios, Michael J. EOP/OSTP; Lattimore, Tracie B. EOP/OSTP; Lin, Merry S. EOP/WHO; McKenna, Michael A. EOP/WHO; Merkel, Theo W. EOP/WHO; Miles, Aaron R. EOP/OSTP; Olmem, Andrew J. EOP/WHO; Pataki, Tim A. EOP/WHO; Ray, Paul J. EOP/OMB; Wong, Anna W. EOP/CEA; Walters, William; Bonner, Maria K. EOP/WHO; Sinclair, Michael R. EOP/NSC; DL NSC WMD; gary.c.rasicot (b)(6) amie.kalsbeek@dot.gov; Naar, Alex (FAA); Firoved, Aaron; Limage, Julia; Seffel, Gary A. EOP/NSC; Robert R. Redfield (olx1@cdc.gov); Waterman, Paige E. EOP/OSTP; Waterman, Elijah J. EOP/NSC; Watson, Ian D. EOP/OSTP; Biles, Amber D CDR USN OSD OUSD POLICY (USA); Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; Marks, Peter; Mair, Michael; Kadlec, Robert (OS/ASPR/IO); Lawrence.Kerr@hhs.gov; Grigsby, Garrett (HHS/OS/OGA); Gary.Disbrow@hhs.gov; Tobert, Gwen M; Scovitch, Joseph R; Costello, Kelly E; DL NSC IO; DL NSC Asia; DL NSC Press; DL NSC Resilience; DL NSC HSA FO Staff; DL NSC Legislative; DL NSC BATS; Redd, John (OS/ASPR/SPPR); Cornett, Elizabeth A CIV (USA); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA); Gulati, Neetu; Liebschutz, Jennifer E. EOP/OMB; Farquharson, Christine E. EOP/OMB; lmize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden; Boney, Virginia M. EOP/WHO; Tully, Ryan M. EOP/NSC; Frater, Eric M; Christ, Katelyn E. EOP/NSC; Weinberger, Collin (OS/OGA) (CTR); Landrum, Ryan P. EOP/NSC; Rault, Nick M. EOP/NSC; Hanna, Cory M. EOP/NSC; Burton, Nicholas S. EOP/OMB; Garufi, Marc A. EOP/OMB; Mroz, Sara K. EOP/NSC; Wade, Dave S. EOP/NSC; Troye, Olivia EOP/NSC; Carlson, Eric J; McGowan, Robert (Kyle) (CDC/OD/OCS); Lowry, Patrick J. EOP/NSC; Cartin, Josh M. EOP/NSC; Kanapathy, Ivan J. EOP/NSC; Elvander, Erika (OS/OGA); Cavanaugh, Brian J. EOP/NSC; Bakewell, Richard A; Thomas, Gloria (HHS/OS/OGA); Butler, Jay C. (CDC/DDID/OD); Bright, Rick (OS/ASPR/BARDA); Ruggiero, Anthony J. EOP/NSC; Brett Armstrong - D1R; paul.detitta@gsa.gov; Marwaha, Brianne C; Carstens, Virgil W; Hassell, David (Chris) (OS/ASPR/IO); McMillin, Virginia D. EOP/WHO; Telle, Adam R. EOP/WHO; Sugarman, AJ J. EOP/WHO; Planning, David M. EOP/WHO; Feddersen, Brett (FAA); Padget, Larry G; Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov); Baehr,

James S. EOP/WHO; Magrino, Christopher; debbie.w.seguin (b)(6) william.ferrara (b)(6) Tobin, Elizabeth D. EOP/NSC; Jonas, Seth H. EOP/NSC; Martin, Gregory J; Music, Chris G. EOP/OMB; Ali, Nausher; Burris, Meghan K. EOP/WHO; Henning, Alexa A. EOP/WHO; Daravi, Roma S. EOP/WHO; Horstman, John H. EOP/WHO; MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA); Wilson, John Mark M. EOP/NSC; Martin, Michael E. EOP/NSC; donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC; Gray, Alexander B. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Stahlman, James E CIV OSD OUSD POLICY (USA); Ullyot, Jonathan L. EOP/NSC; Stufft, Julie M. EOP/NSC; Doster, Kim M. EOP/OSTP; Stimson, Brian (HHS/OGC); Browne, Lisa Y. EOP/NSC; Davis, May M. EOP/WHO; Lekan, Scott (ACF); Chafin, Kelly B. EOP/NSC; Bailey, Drew M. EOP/OMB; Thallam, Satya P. EOP/OMB; Allen, Ronald G. EOP/NSC; Schuchat, Anne MD (CDC/OD); Bain, Ally P. EOP/OMB; Schmoyer, Michael (OS/ONS); Lepore, Loretta (CDC/OD/OCS); alexandra.doumas@usdoj.gov; Hinton, Denise; Champagne, Joshua D. EOP/NSC; Mesquita, Mario M; Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA); DL Chief of Staff Office; Ash, Deborah J. EOP/NSC; Decker, Matthew G. EOP/NSC; Carter, Hillary H. EOP/NSC; Reilly, Tom M. EOP/OMB; Havranek, John; Dumm, Christopher M; FORET, VERNON T; Ellis, Michael J. EOP/WHO; Blue, Matthew (ODAG); JACKSTA, LINDA L; Parra, Yolanda A; Galkowski, James J. EOP/WHO; Tokumasu de Silva, Miriam E
Subject: Novel Coronavirus (b)(5)
When: Wednesday, February 5, 2020 1:00 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: WHSR JFK

Dear Colleagues,

SAP Ruggiero will convene a nCoV (b)(5) on **February 5, 2020, from 1:00-2:30 PM**. With exception of CDC Atlanta, NIAD, and FDA there will be no SVTC. Due to space constraints we ask that departments and agencies, as well as EOP components, send the minimum number of participants. Accordingly, individuals attending this meeting must have the authority to speak on the behalf of their organization.

Please use the WAVES link to register for attendance. (b)(6)

Lauren

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/5/2020 9:29:06 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]
CC: Yates, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=081b97a18deb4148aa33e27729e0cb7c-Thomas.Yate]
Subject: FW: 5 February Novel Coronavirus (b)(5) **Agenda***
Attachments: nCoV Feb (b)(5) Agenda_FINAL.docx

FYI

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: Wednesday, February 5, 2020 9:25 AM
Subject: 5 February Novel Coronavirus (b)(5) ***Agenda***

Colleagues,

Please find attached the agenda for the (b)(5) hat will take place this afternoon.

Classification of this meeting will be at (b)(5)

Best,

Phil

Philip J. Ferro, PhD, MS
Director for Countering Biological Threats
National Security Council
(b)(6) (O) (b)(6) (cell)
(b)(6)

From: Stark, Angela [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D04B10A5E0EC40FFA2EBFEDD711E83AF-ANGELA.STAR]
Sent: 2/5/2020 12:04:17 PM
To: Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Gibney, Jaycie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=390bd4f246ee4a97ada93d146d6d7276-Jaycie.Gibn]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Abdoo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdoo]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
Subject: RE: FOR URGENT REVIEW: CDC media call script
Attachments: nCoR 2-5-20 Talking Points and QnA (final).docx

All here is the clean final. Thank you for your quick review.

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 11:39 AM
To: Stark, Angela <Angela.Stark@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: CDC media call script

OCC has reviewed (b)(5)

(b)(5)

Thanks!
Dinesh

Dinesh Kumar
Office of the Chief Counsel, FDA
Food and Drug Division, OGC/HHS
White Oak Building 32, Room 4377
10903 New Hampshire Ave.
Silver Spring, MD 20993
T 240 402 0372
(b)(6)

From: Stark, Angela <Angela.Stark@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 11:29 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: CDC media call script
Importance: High

All – This is the last call for script and TP edits. I will be printing the document at 11:45 for Denise, and sending the script portion (p. 1) to CDC at that time. http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/TPs%20and%20QA.docx

Thank you,
Angela

From: Stark, Angela
Sent: Wednesday, February 5, 2020 10:13 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Ross, Jennifer (Jennifer.Ross@fda.hhs.gov) <Jennifer.Ross@fda.hhs.gov>
Subject: FOR URGENT REVIEW: CDC media call script
Importance: High

Hi all,

For your review is the draft script to be read at the top of the CDC media telebriefing. Please include edits in track changes in Sharepoint. http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/TPs%20and%20QA.docx

Starting on page 2 are additional talking points for review on topics we expect could come up during the QA portion of the call for which we want RADM Hinton to be prepared to answer. That will be the primary focus of our call at 10:30 – to discuss the QAs that may come up.

Thanks,
Angela

-----Original Appointment-----
From: Stark, Angela
Sent: Wednesday, February 5, 2020 8:25 AM
To: Stark, Angela; McSeveney, Megan; Gibney, Jaycie; Dennis, Claire; Busch, Marcy; Raza, Mark; Scherf, Uwe; Sapsford, Kim E; Kumar, Dinesh; Beers, Donald; Hinton, Denise; Mair, Michael; Sadove, Elizabeth; Abram, Anna; Anderson, Erika; McMeekin, Judith; Abdoo, Mark; Caliguiri, Laura
Cc: Rath, Prakash (FDA); Finnen, April; Rebello, Heidi; Janik, Heather; Lowe, Toby A; Rogers, Michael; Ross, Jennifer (Jennifer.Ross@fda.hhs.gov)
Subject: Prep call for CDC media telebriefing
When: Wednesday, February 5, 2020 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: OO Conference Room, Building 2, 3rd floor or webex below

All, here is the draft script and talking points for review and discussion on the call:
http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/TPs%20and%20QA.docx

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

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

Host key: (b)(6)

Meeting password: (b)(6)

Join meeting

Join by phone
Tap to call in from a mobile device (attendees only)
+1-210-795-0506 US Toll
+1-877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

The briefing is at 12:15 (b)(5)

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 8:10 AM
To: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: Heads-Up - FDA is planning to participate in today's CDC telebriefing at 12:15

Good morning! Sharing as a heads-up that FDA will be participating in a CDC media telebriefing today, we will be represented by RADM Denise Hinton, around noon. (b)(5)

(b)(5)

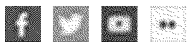
(b)(5) As always, thank you for your help!

Best, Megan

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

Tel: 240-402-4514/ (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Sapsford, Kim E [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=564AA450B77D455B922015ECE2101829-KIS]
Sent: 2/5/2020 12:59:50 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits
Attachments: CDC Press Release - Novel Coronavirus Diagnostic Test Kits for ASPA review 1205 FDA.docx

Sorry I didn't add to Jennifers

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead

Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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Sent: Wednesday, February 05, 2020 12:53 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

I had one comment.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Wednesday, February 05, 2020 12:47 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Subject: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

Hi all – please see some initial edits for me. For CDRH and CBER, please see my edit to suggest (b)(5) (b)(5) For all on chain – please see addition of (b)(5) (b)(5) Thank you!

(b)(5)

(b)(5)

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/5/2020 1:11:40 PM
To: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
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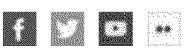
Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits
Attachments: CDC PPress Release - Novel Coronavirus Diagnostic Test Kits for ASPA review 1205 FDA.docx

Hi Kim – no worries – I just added Jennifer's edit to your edits. Thank you!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514 (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Sent: Wednesday, February 05, 2020 1:00 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe

<Uwe.Scherf@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

Sorry I didn't add to Jennifers

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(b)(5)

From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 2/5/2020 1:12:51 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
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Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits
Attachments: CDC Press Release - Novel Coronavirus Diagnostic Test Kits for ASPA review 1205 FDA.docx

I had one edit (incorporated in with Kim's and Jennifer's)

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Sent: Wednesday, February 5, 2020 12:53 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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(b)(5)

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Sent: 2/5/2020 1:33:16 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
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Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

I have no comments.

Heather L. Agler, Ph.D.
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

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From: McSeveney, Megan
Sent: Wednesday, February 5, 2020 1:14 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

Thanks so much! Megan

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514 (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Wednesday, February 05, 2020 1:13 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

I had one edit (incorporated in with Kim's and Jennifer's)

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 12:53 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: RE: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

I had one comment.

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Sent: Wednesday, February 05, 2020 12:47 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: PLEASE SEE BY ASAP edits due by 2:00pm today - CDC PR re: testing kits

Hi all – please see some initial edits for me. For CDRH and CBER, please see my edit (b)(5) (b)(5) For all on chain – please see (b)(5) (b)(5) Thank you!

(b)(5)

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/5/2020 2:52:20 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Gibney, Jaycie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=390bd4f246ee4a97ada93d146d6d7276-Jaycie.Gibn]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: For OCC, OCET and CDRH review URGENT - 3pm deadline re: CLEARANCE_0112: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness
Attachments: QSO 20-XX-CLIA_EUA_2019_nCoV.v4.docxFDA020520.docx

Hi Liz and others – can you please review this version with edits from Jennifer Ross. Jennifer, can you confirm I did not lose any of your edits. Thank you!

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514 **(b)(6)**
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Wednesday, February 05, 2020 2:48 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Subject: RE: For OCC, OCET and CDRH review URGENT - 3pm deadline re: CLEARANCE_0112: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness

A few edits attached. Thanks.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 2:39 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For OCC, OCET and CDRH review URGENT - 3pm deadline re: CLEARANCE_0112: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness

I had a few comments.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Wednesday, February 05, 2020 2:28 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: For OCC, OCET and CDRH review URGENT - 3pm deadline re: CLEARANCE_0112: CMS - Information for

Healthcare Facilities Concerning Coronavirus Illness
Importance: High

Please see – attached already contains edits and comments for review.

(b)(5)

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Sent: 2/5/2020 2:53:48 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Gibney, Jaycie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=390bd4f246ee4a97ada93d146d6d7276-Jaycie.Gibn]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
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Subject: RE: For OCC, OCET and CDRH review URGENT - 3pm deadline re: CLEARANCE_0112: CMS - Information for Healthcare Facilities Concerning Coronavirus Illness

I think Liz's version was fine. Thanks!

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Sent: Wednesday, February 05, 2020 2:52 PM
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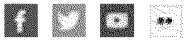
Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514 (b)(6)
Megan.McSeveney@fda.hhs.gov



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(b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/5/2020 3:05:00 PM
To: Bahl, Sunanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eebd62753cf7484d8872b6db91a5b863-BAHLS]
Subject: RE: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

Thanks Sunanda!

From: Bahl, Sunanda <Sunanda.Bahl@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 3:04 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

See article below – great job!

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Wednesday, February 5, 2020 2:11 PM
To: Bahl, Sunanda <Sunanda.Bahl@fda.hhs.gov>
Subject: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

By David Lim

02/05/2020 02:09 PM EST

The CDC today is starting to ship Wuhan coronavirus diagnostic test kits to public health laboratories, likely accelerating efforts to detect new cases.

The diagnostic, which received emergency use authorization from the FDA Tuesday, will allow states to begin reporting confirmed cases without first sending samples to CDC headquarters in Atlanta, according to Nancy Messonnier, CDC's director of the Center for the National Center for Immunization and Respiratory Diseases.

The agency will initially send 200 diagnostic kits to U.S. labs and another 200 to international laboratories, Messonnier told reporters. Each kit can test 700-800 patient samples, she said.

"Distribution of these tests will improve the global capacity to detect and respond to this new virus, as well as greatly enhance our national capacity," Messonnier said. "Availability of this test is a starting place for greater commercial availability of diagnostic testing for nCoV."

Government officials said it will take a few days before the labs complete verification and begin reporting out cases. More test kits are being manufactured and will be made available for distribution, but each laboratory will only receive one test kit for the time being, according to Messonnier.

FDA Chief Scientist Denise Hinton said the agency has provided 35 diagnostic developers specifications for the data that needs to be developed for an application for emergency use authorization, which is intended to expedite the development of additional tests.

To view online:
https://subscriber.politicopro.com/health-care/whiteboard/2020/02/cdc-sending-hundreds-of-coronavirus-testing-kits-to-us-foreign-labs-3976348

From: Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]
Sent: 2/5/2020 3:50:29 PM
To: Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]

Subject: Cap Hill staff Cov Briefing
Attachments: nCoR 2-6-20 Talking Points and QnA (final).doc x
Location: WO1, RM 3317 OR Call-In: 877-369-5243 **(b)(6)**

Start: 2/6/2020 11:30:00 AM
End: 2/6/2020 12:30:00 PM
Show Time As: Busy

Required Attendees: Mair, Michael; McSeveney, Megan; Rath, Prakash (FDA); Mayo Shirley - FDA; Hinton, Denise; Karas Gross (Karas.Gross@fda.hhs.gov); Andrew Tantillo (Andrew.Tantillo@fda.hhs.gov)

NIAID Briefer: Dr. Hilary Marston, Medical Officer and Policy Advisor for Global Health, NIAID Office of the Director
FDA Briefer: RADM Denise Hinton, Chief Scientist

Run of show (Laura Pence is moderating)

(b)(5)

(b)(5)

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/5/2020 4:41:06 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: DRAFT FDA SITREP 05 FEB
Attachments: 10_2019-nCoV Outbreak_FDA SITREP_05 February 2020.docx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/5/2020 4:42:17 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: Supply Chain Summary

Thank you, Courtney!

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 4:37 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Re: Supply Chain Summary

One more thing: Dr. Kadlec would like to hold an HHS DLG (Disaster Leadership Group) meeting on supply chains (possibly this Friday, but I haven't seen any new info).

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: February 5, 2020 at 4:25:00 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Supply Chain Summary

I hope this helps! And apologies if it's too detailed.

(b)(5)

(b)(5)

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/5/2020 4:49:19 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: RE: DRAFT FDA SITREP 05 FEB
Attachments: 10_2019-nCoV Outbreak_FDA SITREP_05 February 2020.docx

Importance: High

Sorry – use this version

From: Mair, Michael
Sent: Wednesday, February 5, 2020 4:41 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: DRAFT FDA SITREP 05 FEB

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/5/2020 5:00:03 PM
To: Hinton, Denise (Denise.Hinton@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=HINTOND]
Subject: Document1
Attachments: Document1.docx

From: Flowers, Louis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE710C32D7BB43CE8006873A92FB3BAF-FLOWERSL]
Sent: 2/5/2020 5:08:57 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

Good stuff!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 3:22 PM
To: Flowers, Louis <Louis.Flowers@fda.hhs.gov>
Subject: FYI: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

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From: Stark, Angela <Angela.Stark@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 2:18 PM
Subject: FW: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

FYI only. See reference to Denise's line on the call about 35 test developers requesting info.

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Wednesday, February 5, 2020 2:10 PM
To: Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

By David Lim

02/05/2020 02:09 PM EST

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You received this POLITICO Pro content because your customized settings include: Public Health. To change your alert settings, please go to https://subscriber.politicopro.com/settings.

This email was sent to angela.stark@fda.hhs.gov by:
POLITICO, LLC
1000 Wilson Blvd.
Arlington, VA 22209
USA.

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/5/2020 5:51:07 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Singh, Patrice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f541d08e079464ba70929944bb73b30-Patrice.Sin]
CC: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; briefingOL@sharepoint.fda.gov

Subject: CONFIRMED CALL: Coronavirus briefing - HELP LAs
Attachments: nCoR 2-6-20 Talking Points and QnA (final).docx
Location: WO-1/3317 :Anna to dial in 866-619-0169 Passcode: (b)(6)

Start: 2/6/2020 2:30:00 PM
End: 2/6/2020 3:00:00 PM
Show Time As: Busy

Required Attendees: Abram, Anna; Gross, Karas; Anderson, Erika; Aguilar, Paul; Pennington, Caitlin; Hinton, Denise; Mair, Michael; McSeveney, Megan; Singh, Patrice

- Attached, FDA QA doc – minor updates highlighted

Today's call
- ASL will open the call

- CDC and ASPR provide very brief updates then open for questions
  - CDC: Stephen C. Redd, MD (RADM, USPHS), Deputy Director for Public Health Service and Implementation Science (DDPHSIS) and Center for Preparedness and Response (CPR),
  - ASPR: Bryan Shuy, Deputy Assistant Secretary/ASPR Chief of Staff

- NIH and FDA to be on the call for the Q&A to answer any questions specific to their agencies.
  - FDA: Anna Abram, Deputy Commissioner for Policy, Legislation, and International Affairs, FDA
  - NIH: Hilary Marston, Medical Officer and Policy Advisor for Global Health, NIAID Office of the Director.

Dial in: 866-619-0169

Passcode: (b)(6)

ASL Leader Code: (b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/5/2020 7:52:56 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: RE: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

Thank you

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 4:24 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

It was easy–you were a pro!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 3:17 PM
To: Stark, Angela <Angela.Stark@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

I sincerely appreciate all of you for drafting talking points and prepping me – THANK YOU!

Denise

From: Stark, Angela <Angela.Stark@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 2:18 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: FW: CDC sending hundreds of coronavirus testing kits to U.S., foreign labs

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From: POLITICO Pro Health Care <politicoemail@politicopro.com>
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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/5/2020 7:55:35 PM
BCC: Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Nabakowski, Andrei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c8bcecc310c4e45a5012d47d40886e1-NABAKOWSKIA]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]
Subject: FDA nCoV Update February 5, 2020
Attachments: 10_2019-nCoV Outbreak_FDA SITREP_05 February 2020.docx

Dear colleagues,

Attached, for your situational awareness, is current FDA information regarding the Coronavirus outbreak.

If you or your technical experts have inputs to help inform, please send to Michael Mair before 3:00 PM daily.

Please be discerning when disseminating further to your staff as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks to all of you for your support.

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Internal, confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/5/2020 8:09:26 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
Subject: RE: Supply Chain Summary

Will do – much appreciated

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 8:05 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Supply Chain Summary

That's great, and thank you. If there's anything I can do to help prep for any of tomorrow's meetings, just let me know. Have a nice evening!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: February 5, 2020 at 7:25:26 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: Supply Chain Summary

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From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 4:37 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Re: Supply Chain Summary

One more thing: Dr. Kadlec would like to hold (b)(5) meeting on (b)(5) (possibly this Friday, but I haven't seen any new info).

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Date: February 5, 2020 at 4:25:00 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Supply Chain Summary

I hope this helps! And apologies if it's too detailed.

(b)(5)

(b)(5)

(b)(5)

From: Cho, David S (CBER) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D47AF9D991AF4C1FBF7CB4C1D287F83E-CHOD]
Sent: 2/6/2020 2:24:41 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
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Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Hi Megan,
With input from Dr. Marks, here is our recommended response to Question 2.
Thanks,
David

"The FDA is fully engaged and an active participant in the federal government's response efforts to develop vaccines against the Novel Coronavirus, working closely with all levels of government partners as well as meeting with any sponsors interested in developing vaccines against the virus."

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To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>
Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Hi all – some edits below for consideration on top of what Heidi shared for Q1. We can check with Dr. Marks, as well and David and David to see if CBER has any more to add for Q2. Heidi and others – thoughts?

For the first q:

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

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Sent: Thursday, February 06, 2020 1:59 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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(b)(5)

For the second q:

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Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Adding David Cho and David Rouse for CBER. Thanks.

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Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Some quick thoughts…

I spoke to Peter the other day **(b)(5)**

(b)(5)

(b)(5)

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Subject: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Good afternoon – Laurie McGinley of the Washington Post just wrote to ask two questions - is Dr. Hahn going to the White House meeting on the coronavirus today? Trying to figure out if the FDA is involved." **(b)(5)**

She is also asking if we "have any information about FDA efforts to fast track vaccines? I'm getting asked that and I checked your fact sheet but I'm not sure I have the answer." **(b)(5)**

(b)(5)

Thank you!

From: Rouse, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=185BAE767862490D88EDA44DB74A75B3-ROUSED]
Sent: 2/6/2020 2:47:40 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
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Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Hi Megan,

Looks good.

Thanks,
Dave

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Thursday, February 6, 2020 2:44 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Hi all – for awareness below are the consolidated Q1 and Q2 responses. Please let me know if I messed anything up while consolidating by 3:30pm. I plan to send these now to OCC for a quick legal review. Thanks!

(b)(5)

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel (b)(6)
Megan.McSeveney@fda.hhs.gov

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Sent: Thursday, February 06, 2020 2:25 PM
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Subject: RE: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Got it. (b)(5) Thanks!

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Sent: Thursday, February 6, 2020 2:24 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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See further revision below

(b)(5)	
(b)(5)	See bracket below.

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Hi all – some edits below for consideration on top of what Heidi shared for Q1. We can check with Dr. Marks, as well and David and David to see if CBER has any more to add for Q2. Heidi and others – thoughts?

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(b)(5)

(b)(5)

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Cc: Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Media Inquiry Re; Commissioner Hahn and WH meeting today on Coronavirus

Good afternoon – Laurie McGinley of the Washington Post just wrote to ask two questions - is Dr. Hahn going to the White House meeting on the coronavirus today? Trying to figure out if the FDA is involved." (b)(5)

She is also asking if we "have any information about FDA efforts to fast track vaccines? I'm getting asked that and I checked your fact sheet but I'm not sure I have the answer." (b)(5)
(b)(5)

Thank you!

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/6/2020 5:13:08 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Fwd: DLG agenda
Attachments: DLG TPs_07 FEB 2020.docx

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: February 6, 2020 at 2:30:00 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: DLG agenda

How this? Happy to change as needed – thx.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 6, 2020 1:03 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: DLG agenda

Thanks, Denise.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, February 6, 2020 1:03 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: DLG agenda

Of course – will do.

Thanks,

Denise

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 6, 2020 1:01 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: DLG agenda

Denise, can you please have [(b)(5)] [(b)(5)] We will need to get them to him this evening so copying in Colin and Keagan for their awareness as well.

[(b)(5)] Thanks in advance.

From: Abram, Anna
Sent: Thursday, February 6, 2020 12:59 PM
To: 'Wolf, Laura (OS/ASPR/SIIM)' <Laura.Wolf@hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: DLG agenda

Dr. Hahn will join so Denise and I will defer to the Commissioner to provide the 2 minute update for FDA.

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Thursday, February 6, 2020 11:28 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: DLG agenda

Anna-

Since the DLG is only half an hour, there are 2 minutes available for fda update (and 2 for sns and pcc as well). [(b)(5)] [(b)(5)]

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.sgov.gov
Desk: 202-260-0666
Cell [(b)(6)]

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/6/2020 5:31:27 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Fwd: 06 FEB SITREP
Attachments: 11_2019-nCoV Outbreak_FDA SITREP_06 February 2020.docx

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From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 6, 2020 at 5:22:22 PM EST
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: 06 FEB SITREP

Attached please find today's COV sit rep

Internal confidential

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/6/2020 6:45:18 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Requests for SITREP - 11_2019-nCoV Outbreak_FDA SITREP_06 February 2020.docx -
Attachments: 11_2019-nCoV Outbreak_FDA SITREP_06 February 2020.docx

Smile

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/6/2020 9:57:15 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
Subject: RE: O'Neill building
Attachments: 20200205-nCOV Supply Chain-DLG-Agenda-FINAL.docx; DLG TPs_07 FEB 2020.docx

Hi Prakesh.

Thanks for following up. The meeting invitation was updated to include the address and it's in the ASPR Main Conference Room, 638G, Humphrey Building. I can find my way there. Attached is the agenda and TPs for your reference. I'm thinking more substantive TPs would be needed based on the agenda, but Anna knows best.

Thanks again for your support – very much appreciated!

Denise

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Thursday, February 6, 2020 9:44 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: O'Neill building

Hi Denise,

I meant to get back to you earlier, I haven't been to the O'Neill building before and was confusing that with Humphrey. However, I'm sure someone could locate the FDA swing space in that building and give you the code since you will have your badge. Also, I'm sure Anne.Tatem@hhs.gov would be able to help you if need be. Sorry I couldn't be more helpful.

Prakash

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/6/2020 10:05:02 PM
To: Abram, Anna [Anna.Abram@fda.hhs.gov]
Subject: DLG Agenda and TPs
Attachments: 20200205-nCOV Supply Chain-DLG-Agenda-FINAL.docx; DLG TPs_07 FEB 2020.docx

Hi Anna,

The meeting invitation was updated to include the agenda. I anticipate CDC will provide substantive comments regarding the PPE Supply Chain Analysis and guidance. The Commissioner's TPs won't directly address those points.

Thanks again for your leadership and support – very much appreciated!

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/7/2020 8:17:55 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]
Subject: DLG Agenda and TPs
Attachments: 20200205-nCOV Supply Chain-DLG-Agenda-FINAL.docx; DLG TPs_07 FEB 2020.docx

Good morning!

I just got off the phone with Anna. In preparation for the DLG this afternoon, could you get more specific PPE TPs from Suzanne/CDRH on the Supply Chain so the Commissioner has back TPs to refer to as needed. Perhaps, you can add to the comprehensive list you created yesterday if there is anything more specific. Your preference.

Many thanks!

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/7/2020 8:23:15 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]
Subject: FW: DLG Agenda and TPs
Attachments: 20200205-nCOV Supply Chain-DLG-Agenda-FINAL.docx; DLG TPs_07 FEB 2020.docx; FDA Supply Chain Talking Points.2.6.20.docx

Attachment with your TPs

From: Hinton, Denise
Sent: Friday, February 7, 2020 8:18 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: DLG Agenda and TPs

Good morning!

I just got off the phone with Anna. In preparation for the DLG this afternoon, could you get more specific PPE TPs from Suzanne/CDRH on the Supply Chain so the Commissioner has back TPs to refer to as needed. Perhaps, you can add to the comprehensive list you created yesterday if there is anything more specific. Your preference.

Many thanks!

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/7/2020 8:41:26 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: RE: DLG Agenda and TPs
Attachments: FDA Supply Chain Talking Points.2.6.20.docx

Hi Anna,

We'll work on providing more specific TPs for PPEs. Attached is a running list Brooke Courtney (OCS/OCET) put together to date.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 6, 2020 10:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: DLG Agenda and TPs

Thanks, Denise. Can we get some more specific PPE tps from Suzanne/CDRH so we have more on this headed into tomorrow's DLG?

Thanks for everything you are doing on CoV. I know you are working non-stop on this front.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: February 6, 2020 at 10:05:03 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: DLG Agenda and TPs

Hi Anna,

The meeting invitation was updated to include the agenda. I anticipate CDC will provide substantive comments regarding the PPE Supply Chain Analysis and guidance. The Commissioner's TPs won't directly address those points.

Thanks again for your leadership and support – very much appreciated!

Denise

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 2/7/2020 8:57:48 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: DLG Agenda and TPs
Attachments: 20200205-nCOV Supply Chain-DLG-Agenda-FINAL.docx; DLG TPs_07 FEB 2020.docx; FDA Supply Chain Talking Points.2.6.20.docx

Good morning—I'm copying Liz since I'm teaching at Georgetown today. My apologies! Brooke

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From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 07, 2020 8:23 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FW: DLG Agenda and TPs

Attachment with your TPs

From: Hinton, Denise
Sent: Friday, February 7, 2020 8:18 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: DLG Agenda and TPs

Good morning!

I just got off the phone with Anna. In preparation for the DLG this afternoon, could you get more specific PPE TPs from Suzanne/CDRH on the Supply Chain so the Commissioner has back TPs to refer to as needed. Perhaps, you can add to the comprehensive list you created yesterday if there is anything more specific. Your preference.

Many thanks!

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/7/2020 9:45:42 AM
To: Schwartz, Suzanne [Suzanne.Schwartz@fda.hhs.gov]
Subject: DLG Agenda and TPs
Attachments: 20200205-nCOV Supply Chain-DLG-Agenda-FINAL.docx; DLG TPs_07 FEB 2020.docx

FYI

From: Hinton, Denise
Sent: Friday, February 7, 2020 8:18 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: DLG Agenda and TPs

Good morning!

I just got off the phone with Anna. In preparation for the DLG this afternoon, could you get more specific PPE TPs from Suzanne/CDRH on the Supply Chain so the Commissioner has back TPs to refer to as needed. Perhaps, you can add to the comprehensive list you created yesterday if there is anything more specific. Your preference.

Many thanks!

Denise

From: Maycock, Brett (OS/ONS) [Brett.Maycock@hhs.gov]
Sent: 2/7/2020 10:04:40 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]
Subject: HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #52)
Attachments: ASPR Tier 3 SLB nCoV 06Feb20 1700ET.pdf; FINAL - CDC Novel Coronavirus nCoV SITREP 010 02-06-2020.pdf

Ma'am,

Good morning. Please see the attached ASPR slide related to some our discussion on the supply chain and many of the HHS task forces working on potential gaps. Please let me know if you have any questions.

Thanks,

Brett

Brett Maycock
ONS nCoV Response Commander
Senior Advisor for Homeland Security
CAPT, United States Public Health Service
Office of National Security (ONS)
U.S. Department of Health & Human Services
Cell (b)(6)
Unclassified email: Brett.Maycock@hhs.gov

From: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Sent: Thursday, February 6, 2020 9:10 PM
To: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Subject: HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #52)

UNCLASSIFIED // FOR OFFICIAL USE ONLY

HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #52)

Source: HHS, CDC

What: As of **06Feb20, 28,275 cases of confirmed 2019-nCoV in 28 locations worldwide.**

- As of **06Feb20, 17,237** domestic travelers have been screened; with 12 confirmed cases in U.S.(1-Arizona,1-Massachusetts , 6-California, 2-Illinois, 1-Washington, 1- Wisconsin).
- **Japanese cruise ship Diamond Princess has reported that 20 passengers and crew have tested positive for 2019-nCoV, including 3 Americans.**
- **Wave 2 evacuations currently underway**
- **Two additional planes have departed from Wuhan and will arrive in the US on 07Feb20.**
- **CDC-developed laboratory test kit to detect 2019-nCoV**
  - **Shipping began 05Feb20 to select qualified U.S. and international laboratories.**

Global Case Counts
- Total global confirmed cases = **28,275**

- Total global confirmed deaths = **565**
- New Cases (~24 hrs.) = **3,723**
- Countries with cases = 28

HHS Posture
- HHS SOC remains activated at Level 1 (24/7)
- CDC EOC remains activated (Agency Wide)
- HHS IMT personnel deployed to repatriation sites across U.S.

For more details, please see attached HHS SLB for Novel Coronavirus which includes the **06Feb20** CDC SITREP for Novel Coronavirus.

When: **06Feb20 2110ET**

Where: International

Why: CIR: Disease- International

Actions/Follow-Up: The SOC will continue to monitor this incident and report as needed**.** *This message was distributed to the 2019 nCoV IMT, 2019 nCoV Interagency, 2019 nCoV IST, 2019 nCoV Senior Leadership Distribution Lists.*

Prepared by: Juan Ospina, Watch Officer
Approved by: RHibano Dokong, Senior Watch Officer

Secretary's Operations Center
U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/7/2020 11:04:05 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]
Subject: RE: Coronavirus Press Conference Today
Attachments: nCoR 2-6-20 Talking Points and QnA (final).docx

Here are latest TPs and QA **(b)(5)** Please let me know if you want to add anything to this by 11:30 a.m. Thank you!

nCoR 2-6-20 Talking Points an...

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 7, 2020 10:59 AM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Coronavirus Press Conference Today

Noted -thanks

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 10:57 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Coronavirus Press Conference Today

We are pulling the latest TPs for the Commissioner. Will run by you quickly.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 7, 2020 10:55 AM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Coronavirus Press Conference Today

Thanks

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 10:50 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: FW: Coronavirus Press Conference Today
Importance: High

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Friday, February 7, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Sherman, Jennifer (OS) <Jennifer.Sherman@hhs.gov>; Heck, Mia (OS) <Mia.Heck@hhs.gov>; Thorman, Caroline (ACF) <Caroline.Thorman@acf.hhs.gov>; Wassink, Bradley (ACF) <Bradley.Wassink@acf.hhs.gov>
Cc: Stecker, Judy (OS) <Judy.Stecker@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Brennan, Patrick (OS) <Patrick.Brennan@hhs.gov>; Pratt, Michael (OS) <Michael.Pratt@hhs.gov>; Tignor, Beth (OS) <Beth.Tignor@hhs.gov>
Subject: Coronavirus Press Conference Today
Importance: High

Hello FDA, Surgeon General's office, and ACF—

Today at 2pm, there will be a press conference in the HHS small auditorium on the Coronavirus. We ask that your principals please attend and sit in the front row. They may be asked to answer questions that pertain to their portfolios.

We have not advised the event yet and will forward once the advisory goes out.

Please have your principal arrive by no later than 1:45 PM.

Call with any questions **(b)(6)** Thx!

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/7/2020 11:07:51 AM
To: 'Denise Hinton' [dhinton6@icloud.com]
Subject: TPs
Attachments: nCoR 2-6-20 Talking Points and QnA (final).docx

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/7/2020 11:31:27 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: FW: [Inform] ASPR RPD WG Final Report (Includes Modeling and Control Banding)
Attachments: RPD ICDc - FINAL.pdf

FYI

From: Agler, Heather L <Heather.Agler@fda.hhs.gov>
Sent: Friday, February 7, 2020 11:28 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Subject: FW: [Inform] ASPR RPD WG Final Report (Includes Modeling and Control Banding)

Attached is the report that came out in 2015 from the RPD Working Group. I think this is likely some of the information that Anita Patel will be discussing at the DLG. She discussed some of this information and mentioned the report during the ASPR Supply Chain Task Force Meeting on Monday.

Robert – Suzanne said the issue of reuse is discussed in this document as well.

Thanks,
Heather

Heather L. Agler, Ph.D.
Innovation Program
All-Hazards Readiness, Response, and Cybersecurity (ARC) – *formerly EMCM*
Division of All-Hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
(p) 301-796-6340
Heather.Agler@fda.hhs.gov

From: Ross, Aftin
Sent: Friday, February 7, 2020 10:52 AM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Cc: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Simone, Lisa <Lisa.Simone@fda.hhs.gov>; Block, Frank <Frank.Block@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Subject: [Inform] ASPR RPD WG Final Report (Includes Modeling and Control Banding)

Good afternoon. One of the asks from Suzanne and Heather to better inform discussions that were coming up on the supply chain task force calls is the final report from the RPD WG. Please see the attached report and email below for additional context.

Best,

Aftin

Aftin Ross, Ph.D.
Senior Project Manager
Senior Science Health Advisor
Team: All-Hazards Readiness Response and Cybersecurity (ARC)
Division: All hazards Response, Science and Strategic Partnerships (DARSS)
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health
U.S. Food and Drug Administration

WO 66, Room 5558
10903 New Hampshire Ave, Silver Spring, MD 20993
Office: 301-796-5679; Cell: (b)(6)
aftin.ross@fda.hhs.gov

From: Ireland, Karen (OS/ASPR) (CTR) <Karen.Ireland@hhs.gov>
Sent: Thursday, May 07, 2015 1:32 PM
To: Andrew Levinson <levinson.andrew@dol.gov>; Baccam, Prasith (OS) <Prasith.Baccam@hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Crawford, Richard (OS) <Richard.Crawford@hhs.gov>; Da Silva Carias, Cristina Maria (CDC*) <vnn9@cdc.gov>; Curren, Stephen (OS) <Stephen.Curren@hhs.gov>; D'Alessandro, Maryann M (CDC) <bpj5@cdc.gov>; Hill-Harmon, Mary (OS) <Mary.Hill-Harmon@hhs.gov>; Hrdina, Chad (OS) <Chad.Hrdina@hhs.gov>; Ireland, Karen (OS) <Karen.Ireland@hhs.gov>; Janet Carter <carter.janet@dol.gov>; Kruk, Jennifer (OS) <Jennifer.Kruk@hhs.gov>; Lant, Timothy (OS) <Timothy.Lant@hhs.gov>; Lewis Radonovich <lewis.radonovich@med.va.gov>; Maher, Carmen <Carmen.Maher@fda.hhs.gov>; Meltzer, Martin I (CDC) <gzm4@cdc.gov>; McClimans, David (OS) <David.McClimans@hhs.gov>; Mcdowell, Heather <Heather.Mcdowell@fda.hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Rasmussen, Sonja (CDC) <skr9@cdc.gov>; BerryAnn, Roland J (CDC) <rfb6@cdc.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Stallings, Helen (OS) <Helen.Stallings@hhs.gov>; Thakur, Nikhil <Nikhil.Thakur@fda.hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Wencil, Elaine (OS) <Elaine.Wencil@hhs.gov>
Subject: Signed RPD WG document

Good afternoon,

Congratulations RPD WG! Attached for your records is the final signed Integrated Capabilities Document: RPD and Facemask Chapter. Dr. Lurie's sole comments focused on innovation, and she concurred with the approach specified in the systems capabilities section of the document. This email serves as an official sun-setting of the PHEMCE All-Hazards RPD Working Group. We might hold one last in-person only meeting in June if you are able to attend. Details to follow in a separate email.

Our document called for next steps (with proposed leads) to include:

- Requirements analyses: ASPR/OPP/MCSR

- Acquisition strategies and plans: CDC
- Continued regulatory harmonization: CDC & FDA
- Innovation: VA & ASPR/BARDA
- Guidance documents: all agencies

RPD WG members may be called upon to help address the follow-on steps as needed.

As always, we appreciate all of your input and participation within the RPD WG and hope to continue working with you on other (potentially related) projects in the future.

Best,
Karen

Karen Ireland, MS
Medical Countermeasure Policy Analyst
Gap Solutions, Inc.
Contractor Supporting:
HHS/ASPR/OPP/MCSR
Thomas P. O'Neill Federal Building
200 C Street SW
Washington DC 20024
Phone: 202-691-2012| Blackberry: (b)(6)
Email: karen.ireland@hhs.gov

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/7/2020 12:10:44 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; 2019-nCoV FDA IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1303ad17cce4c95b45c63ac5c0c31df-2019-nCoV F]
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)
Attachments: 4 QA.docx

And, here are the answers to the 3 other questions—pulled from previously cleared language.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:00 PM
To: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5) Can you all get us something within 30 min? Brad and Rosemary – can you lead on this? Michael – please jump in if you prefer to pull something together? Thank you!

From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 2/7/2020 12:20:26 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
Subject: RE: DLG Agenda and TPs
Attachments: CDRH_DLG TPs_07 FEB 2020.docx

Here are the final TPs, including specific PPE TPs for PPE on the second page. Thanks!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 7, 2020 9:24 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: DLG Agenda and TPs

AIC and Liz,

I don't want to duplicate communication efforts, so won't reach out to Suzanne if you are doing so already. Will wait to hear back from you.

Thanks,

Denise

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, February 7, 2020 8:58 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: FW: DLG Agenda and TPs

Good morning—I'm copying Liz since I'm teaching at Georgetown today. My apologies! Brooke

---

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 07, 2020 8:23 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FW: DLG Agenda and TPs

Attachment with your TPs

From: Hinton, Denise
Sent: Friday, February 7, 2020 8:18 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: DLG Agenda and TPs

Good morning!

I just got off the phone with Anna. In preparation for the DLG this afternoon, could you get more specific PPE TPs from Suzanne/CDRH on the Supply Chain so the Commissioner has back TPs to refer to as needed. Perhaps, you can add to the comprehensive list you created yesterday if there is anything more specific. Your preference.

Many thanks!

Denise

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/7/2020 12:24:51 PM
To: Ngan, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7a30838c8bc49428cbbe4959ae8ed6c-NGANK]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; 2019-nCoV FDA IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1303ad17cce4c95b45c63ac5c0c31df-2019-nCoV F]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Many thanks!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:24 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>

Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Dr. Farley from CDER will be responding momentarily with some more specific information that could be conveyed internally only.

Kelly Ngan, CTECS

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:21 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:19 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Don and Liz - will the language I just sent work or can you make edits asap to that? TYhanks

Megan McSeveney
Press Officer

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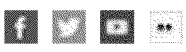

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:17 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Hi all – (b)(5)

(b)(5)

Megan McSeveney
Press Officer

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Megan.McSeveney@fda.hhs.gov

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:14 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:12 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG

<2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

(b)(5) Thank you!

Megan McSeveney
Press Officer

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Tel: 240-402-4514/Cel (b)(6)
Megan.McSeveney@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:09 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Hi – **(b)(5)**

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:09 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

Adding Don.

Thanks.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:00 PM
To: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: URGENT COMMISSIONER NEEDS INFO RE: **(b)(5)** - coronavirus TP asap for Dr. Hahn for HHS presser at 2

(b)(5)

(b)(5) Can you all get us something within 30 min? Brad and Rosemary – can you lead on this? Michael – please jump in if you prefer to pull something together? Thank you!

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/7/2020 12:34:13 PM
To: Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; 2019-nCoV FDA IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1303ad17cce4c95b45c63ac5c0c31df-2019-nCoV F]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5) (b)(5)

+John Farley – we're on the phone

(b)(5)

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Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:32 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Rebello, Heidi

<Heidi.Rebello@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Megan,

(b)(5)

Don

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:23 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Got it – (b)(5) -ok with all?

(b)(5)

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FDA U.S. FOOD & DRUG ADMINISTRATION

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:21 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: **(b)(5)** - coronavirus TP asap for Dr. Hahn for HHS presser at 2 **(b)(5)**

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:19 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: **(b)(5)** - coronavirus TP asap for Dr. Hahn for HHS presser at 2 **(b)(5)**

Don and Liz - will the language I just sent work or can you make edits asap to that? TYhanks

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Megan.McSeveney@fda.hhs.gov

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:17 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: **(b)(5)** - coronavirus TP asap for Dr. Hahn for HHS presser at 2 **(b)(5)**

Hi all – **(b)(5)** Thanks for your patience. **(b)(5)**

(b)(5)

(b)(5)

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U.S. FOOD & DRUG ADMINISTRATION

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:14 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:12 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

(b)(5) Thank you!

Megan McSeveney
Press Officer

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Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:09 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

Hi – (b)(5)

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:09 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: RE: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) r - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5)

Adding Don.

Thanks.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:00 PM
To: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: URGENT COMMISSIONER NEEDS INFO RE: (b)(5) - coronavirus TP asap for Dr. Hahn for HHS presser at 2 (b)(5)

(b)(5) Can you all get us something within 30 min? Brad and Rosemary – can you lead on this? Michael – please jump in if you prefer to pull something together? Thank you!

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 2/7/2020 12:49:30 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2
Attachments: nCoR Talking Points Trimmed.docx

Megan/Anna – does this cover everything?

The other doc was way too much info, IMO given the amount of time we have before the event.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:47 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

+MF

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:46 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Dr. Hahn just asked to see his tps – do we have the other ones ready?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

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Press Officer

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Megan.McSeveney@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:30 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Need ASAP. Thanks.

Sent from my iPhone

On Feb 7, 2020, at 12:11 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

(b)(5) and will send asap.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 11:53 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

HHS just sent me a COV asap request so Megan turning this to you to help keep this moving forward

We need high-level TPs (one on each topic) on what FDA is doing on CoV front with respect to supply chain and the EUA issued this week – OK to pull from what we've used before on these topics as asked/pushed out in recent days

And we need a "if asked" regarding Gilead remdesivir export/use in China

Also an "if asked" regarding impact to inspection work in China

Unfortunately, we need this asap

Thank you in advance

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/7/2020 12:50:53 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: DLG TPs PPE
Attachments: CDRH_DLG TPs_07 FEB 2020.docx

I don't have a place to print so sending so you have as well electronically.

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Date: February 7, 2020 at 12:20:27 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: DLG Agenda and TPs

Here are the final TPs, including specific PPE TPs for PPE on the second page. Thanks!

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/7/2020 1:37:43 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

U.S. FOOD & DRUG ADMINISTRATION

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:36 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

How about this? Stacy and all – is this closer?

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:34 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 7, 2020 at 1:03:54 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

FDA U.S. FOOD & DRUG ADMINISTRATION

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:01 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika

<Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell **(b)(6)**
Megan.McSeveney@fda.hhs.gov

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:00 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5) I am not sure we can get anywhere discussing among ourselves, but I can participate in a call if there is one.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:56 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael

<Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Hi Stacy – I connected with Anna – I'll work with the group on this for the 20-30 min ahead of the presser and see what we can get. John, Don, Michael, Liz and Brad – maybe we can hop quickly on a call and discuss?

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(5)
Megan.McSeveney@fda.hhs.gov

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:52 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:50 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:49 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald

<Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Here you go.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:46 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

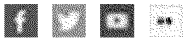
Dr. Hahn just asked to see his tps – do we have the other ones ready?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel **(b)(6)**
Megan.McSeveney@fda.hhs.gov



From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:30 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael

<Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Need ASAP. Thanks.

Sent from my iPhone

On Feb 7, 2020, at 12:11 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

(b)(5) and will send asap.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 11:53 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Unfortunately, we need this asap

Thank you in advance

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/7/2020 1:44:21 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Copy ty.

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

U.S. FOOD & DRUG ADMINISTRATION

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:44 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:41 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Anna and I **(b)(5)**

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:38 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Ce (b)(6)
Megan.McSeveney@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: McSeveney, Megan
Sent: Friday, February 07, 2020 1:36 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

How about this? Stacy and all – is this closer?

(b)(5)

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:34 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Date: February 7, 2020 at 1:03:54 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:01 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
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Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy

<Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

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From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:00 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5) I am not sure we can get anywhere discussing among ourselves, but I can participate in a call if there is one.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:56 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Hi Stacy – I connected with Anna – I'll work with the group on this for the 20-30 min ahead of the presser and see what we can get. John, Don, Michael, Liz and Brad – maybe we can hop quickly on a call and discuss?

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: **(b)(6)**
Megan.McSeveney@fda.hhs.gov

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:52 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:50 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:49 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Here you go.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:46 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Dr. Hahn just asked to see his tps – do we have the other ones ready?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>;

Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Ce **(b)(6)**
Megan.McSeveney@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:30 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Need ASAP. Thanks.

Sent from my iPhone

On Feb 7, 2020, at 12:11 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

(b)(5) and will send asap.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 11:53 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

(b)(5)

Unfortunately, we need this asap

Thank you in advance

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/7/2020 1:46:13 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Thank you

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 7, 2020 at 1:44:00 PM EST
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:41 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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Anna and I **(b)(5)**

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Press Officer

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U.S. Food and Drug Administration
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FDA U.S. FOOD & DRUG ADMINISTRATION

From: McSeveney, Megan
Sent: Friday, February 07, 2020 1:36 PM
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Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

How about this? Stacy and all – is this closer?

(b)(5)

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Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel (b)(6)
Megan.McSeveney@fda.hhs.gov

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Sent: Friday, February 07, 2020 1:34 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 7, 2020 at 1:03:54 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>,

Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:01 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell **(b)(6)**
Megan.McSeveney@fda.hhs.gov

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:00 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5) I am not sure we can get anywhere discussing among ourselves, but I can participate in a call if there is one.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:56 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Hi Stacy – I connected with Anna – I'll work with the group on this for the 20-30 min ahead of the presser and see what we can get. John, Don, Michael, Liz and Brad – maybe we can hop quickly on a call and discuss?

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel (b)(6)
Megan.McSeveney@fda.hhs.gov

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:52 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:50 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:49 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Here you go.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:46 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Dr. Hahn just asked to see his tps – do we have the other ones ready?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
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Megan McSeveney
Press Officer

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U.S. Food and Drug Administration
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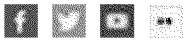
Megan.McSeveney@fda.hhs.gov



From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:30 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Need ASAP. Thanks.

Sent from my iPhone

On Feb 7, 2020, at 12:11 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

(b)(5) and will send asap.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 11:53 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

(b)(5)

Unfortunately, we need this asap

Thank you in advance