



April 30, 2020

Christine H. Monahan
American Oversight
1030 15th Street NW, B255
Washington, DC 20005

RE: FDA FOIA Request 2020-2523;
American Oversight v. HHS et al., Civil No. 20-cv-01063

Dear Ms. Monahan:

This is in response to the Freedom of Information Act (FOIA) request numbers 2020-2523 that is the subject of the Amended Complaint filed in *American Oversight v. HHS et al.*, Civil No. 20-cv-01063, now pending in the U.S. District Court for the District of Columbia.

FDA's Office of the Commissioner sent records to the Department of Health and Human Services and the White House for further review and return to us. That consultation has been completed and the records, FDA-OC-2020-2523-000467 through FDA-OC-2020-2523-000483, are enclosed.

We have withheld portions of these pages under the exemptions provided in 5 U.S.C. §§ 522(b)(5), and (b)(6) of FOIA, as delineated below:

Exemption (b)(5) permits the withholding of inter-agency or intra-agency memoranda or letters that would not be available by law to a party other than an agency in litigation with the agency. This exemption includes communications records which are part of the deliberative process and pre-decisional. Disclosure of such material could inhibit the open and candid expression of opinions and diminish the quality of the decision-making process.

Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption (b)(6) consists of personal information, such as direct contact information, and conference and passcode numbers. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth under exemption (b)(6) to release the personal identifying information of certain third parties.

Please direct any questions regarding this response to Amy Powell of the U.S. Department of Justice, at (919) 856-4013 or Amy.Powell@usdoj.gov.

Sincerely,

Meredith J. Schlaifer, M.S., J.D.
FOIA Officer, Office of the Commissioner
Division of Freedom of Information
U.S. Food and Drug Administration

From: Droegemeier, Kelvin K. EOP/OSTP [(b) (6)]@ostp.eop.gov]
Sent: 4/3/2020 11:05:14 AM
To: Holt, Brandon T. EOP/NSC [(b) (6)]@nsc.eop.gov]; Clancy, Carolyn [Carolyn.Clancy@va.gov]; Klote, Mary M. [Mary.Klote@va.gov]; Justice, Amy [Amy.Justice2@va.gov]; Bates, Jack (BISL) [Jack.Bates@va.gov]; Francis, Joe [Joe.Francis@va.gov]; Quinn, John F. (NDS) [John.Quinn@va.gov]; Box, Tami [Tamara.Box@va.gov]; Ramoni, Rachel [Rachel.Ramoni@va.gov]; Muralidhar, Sumitra [Sumitra.Muralidhar@va.gov]; Brouillette, Dan [dan.brouillette@hq.doe.gov]; Dabbar, Paul [paul.dabbar@hq.doe.gov]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Watson, Ian D. EOP/OSTP [(b) (6)]@ostp.eop.gov]; Waterman, Paige E. EOP/OSTP [(b) (6)]@ostp.eop.gov]; Pottinger, Matthew F. EOP/WHC [(b) (6)]@who.eop.gov]; Fabina, Lauren C. EOP/NSC [(b) (6)]@nsc.eop.gov]; Ruggiero, Anthony J. EOP/NSC [(b) (6)]@nsc.eop.gov]; Tully, Ryan M. EOP/NSC [(b) (6)]@nsc.eop.gov]; Kratsios, Michael J. EOP/OSTP [(b) (6)]@ostp.eop.gov]; Parker, Lynne E. EOP/OSTP [(b) (6)]@ostp.eop.gov]
CC: Hennessey, Millicent S. EOP/NSC [(b) (6)]@nsc.eop.gov]; Ferro, Phil J. EOP/NSC [(b) (6)]@nsc.eop.gov]
Subject: RE: [(b) (5)] Coordination Call between EOP, VA, DoE and FDA

Hi all,

I'm adding Michael Kratsios and Lynne Parker re [(b) (5)]

Kelvin

From: Holt, Brandon T. EOP/NSC <[(b) (6)]@nsc.eop.gov>
Sent: Friday, April 3, 2020 10:36 AM
To: Clancy, Carolyn <Carolyn.Clancy@va.gov>; Klote, Mary M. <Mary.Klote@va.gov>; Justice, Amy <Amy.Justice2@va.gov>; Bates, Jack (BISL) <Jack.Bates@va.gov>; Francis, Joe <Joe.Francis@va.gov>; Quinn, John F. (NDS) <John.Quinn@va.gov>; Box, Tami <Tamara.Box@va.gov>; Ramoni, Rachel <Rachel.Ramoni@va.gov>; Muralidhar, Sumitra <Sumitra.Muralidhar@va.gov>; Brouillette, Dan <dan.brouillette@hq.doe.gov>; Dabbar, Paul <paul.dabbar@hq.doe.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Watson, Ian D. EOP/OSTP [(b) (6)]@ostp.eop.gov]; Waterman, Paige E. EOP/OSTP [(b) (6)]@ostp.eop.gov]; Droegemeier, Kelvin K. EOP/OSTP <[(b) (6)]@ostp.eop.gov>; Pottinger, Matthew F. EOP/WHO [(b) (6)]@who.eop.gov]; Fabina, Lauren C. EOP/NSC [(b) (6)]@nsc.eop.gov]; Ruggiero, Anthony J. EOP/NSC [(b) (6)]@nsc.eop.gov]; Tully, Ryan M. EOP/NSC [(b) (6)]@nsc.eop.gov]
Cc: Hennessey, Millicent S. EOP/NSC [(b) (6)]@nsc.eop.gov]; Ferro, Phil J. EOP/NSC [(b) (6)]@nsc.eop.gov]
Subject: RE: Big [(b) (5)] Coordination Call between EOP, VA, DoE and FDA

Good morning all,

Could we please lock in this call for 12:30pm? Please see call-in information below. Thank you!

Participant Dial-In: (202) 395-6392

Participant Code [(b) (6)]

Best,
Brandon

Brandon T. Holt
Office of the National Security Advisor
D[(b) (6)]

From: Ferro, Phil J. EOP/NSC (b) (6) @nsc.eop.gov>

Sent: Friday, April 3, 2020 10:30 AM

To: Clancy, Carolyn <Carolyn.Clancy@va.gov>; Klote, Mary M. <Mary.Klote@va.gov>; Justice, Amy <Amy.Justice2@va.gov>; Bates, Jack (BISL) <Jack.Bates@va.gov>; Francis, Joe <Joe.Francis@va.gov>; Quinn, John F. (NDS) <John.Quinn@va.gov>; Box, Tami <Tamara.Box@va.gov>; Ramoni, Rachel <Rachel.Ramoni@va.gov>; Muralidhar, Sumitra <Sumitra.Muralidhar@va.gov>; Brouillette, Dan <dan.brouillette@hq.doe.gov>; Dabbar, Paul <paul.dabbar@hq.doe.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Watson, Ian D. EOP/OSTP (b) (6) @ostp.eop.gov>; Waterman, Paige E. EOP/OSTP (b) (6) @ostp.eop.gov>; Droegemeier, Kelvin K. EOP/OSTP <(b) (6) @ostp.eop.gov>; Pottinger, Matthew F. EOP/WHO (b) (6) @who.eop.gov>; Fabina, Lauren C. EOP/NSC (b) (6) @nsc.eop.gov>; Ruggiero, Anthony J. EOP/NSC (b) (6) @nsc.eop.gov>; Tully, Ryan M. EOP/NSC (b) (6) @nsc.eop.gov>

Cc: Holt, Brandon T. EOP/NSC <(b) (6) @nsc.eop.gov>; Hennessey, Millicent S. EOP/NSC (b) (6) @nsc.eop.gov>

Subject: (b) (5) Coordination Call between EOP, VA, DoE and FDA

Good Morning Colleagues,

First off, thank you for your robust support to get this initiative off the ground as quickly as possible. (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

We would like to convene a call this afternoon to coordinate efforts. Brandon Holt who works for APDNSA Pottinger will work with you and your staff to schedule this call. To this end, please feel free to have your staff respond to Brandon. We will send out an agenda shortly.

Please let me know if you have any questions or if I may be of assistance.

All the best,

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: 3/21/2020 11:47:21 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; (b) (6) who.eop.gov
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)
Start: 3/21/2020 12:00:00 PM
End: 3/21/2020 12:30:00 PM
Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 10:04:25 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; (b) (6) who.eop.gov
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)
Start: 3/21/2020 11:30:00 AM
End: 3/21/2020 12:00:00 PM
Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter (b) (6) who.eop.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 11:44:54 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; (b) (6) who.eop.gov
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)
Start: 3/21/2020 12:30:00 PM
End: 3/21/2020 1:00:00 PM
Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFACOCFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 11:20:47 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; (b) (6) who.eop.gov
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)
Start: 3/21/2020 11:45:00 AM
End: 3/21/2020 12:15:00 PM
Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note updated start time of 11:45 AM. Thank you.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 8:01:07 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; (b) (6) who.eop.gov
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)
Start: 3/21/2020 12:00:00 PM
End: 3/21/2020 12:30:00 PM
Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

From: Abernethy, Amy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C84171967C724EE799BB2658197086BC-AMY.ABERNET]
Sent: 3/23/2020 9:01:29 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Liddell, Christopher P. EOP/WHO [(b) (6) who.eop.gov]
CC: Grogan, Joseph J. EOP/WHO [(b) (6) who.eop.gov]; CMS SV1 [(b) (6) cms.hhs.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-(b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbddd983419fcd-HHS-olx1-cd]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]
Subject: Re: Oracle Platform

Hi Chris - Working

From: Hahn, Stephen <(b) (6)@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:59 AM
To: Liddell, Christopher P. EOP/WHO <(b) (6) who.eop.gov>
Cc: Grogan, Joseph J. EOP/WHO <(b) (6) who.eop.gov>; CMS SV1 <(b) (6) cms.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)@niaid.nih.gov>; Collins, Francis S (NIH) <(b) (6)@od.nih.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: Re: Oracle Platform

Chris,
Amy is working on this in real time. We'll get this to you.
Steve

From: Liddell, Christopher P. EOP/WHO <(b) (6) who.eop.gov>
Date: March 22, 2020 at 5:31:29 PM EDT
To: Hahn, Stephen <(b) (6)@fda.hhs.gov>
Cc: Grogan, Joseph J. EOP/WHO <(b) (6) who.eop.gov>; CMS SV1 <(b) (6)@cms.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6)@niaid.nih.gov>; Collins, Francis S (NIH)

<(b) (6)@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

Subject: Re: Oracle Platform

Steve

Do you have a presentation from (b) (5)

Thanks

Chris

On Mar 22, 2020, at 4:00 PM, Hahn, Stephen <(b) (6)@fda.hhs.gov> wrote:

Thanks, Chris. Please let me know if you have any questions.

Steve

From: Grogan, Joseph J. EOP/WHO <(b) (6)@who.eop.gov>

Date: March 21, 2020 at 7:29:35 PM EDT

To: CMS SV1 <SV1@cms.hhs.gov>

Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Fauci, Anthony S (NIH) <(b) (6)@niaid.nih.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Redfield, Robert R (CDC) <olx1@cdc.gov>, Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>, Lane, Henry C (NIH) <(b) (6)@niaid.nih.gov>, Collins, Francis S (NIH) <(b) (6)@od.nih.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Liddell, Christopher P. EOP/WHO <(b) (6)@who.eop.gov>

Subject: Re: Oracle Platform

Cc'ing deputy cos Chris Liddell who can help with any technical issues and can enlist US digital services if necessary.

Sent from my iPhone

On Mar 21, 2020, at 7:02 PM, CMS SV1 <SV1@cms.hhs.gov> wrote:

Amy, please work through Brady Brookes for CMS issues.

From: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Sent: Saturday, March 21, 2020 6:59 PM

To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Hahn, Stephen <(b) (6)@fda.hhs.gov>; Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; CMS SV1 <(b) (6)@cms.hhs.gov>

Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan <(b) (6)@who.eop.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Collins, Francis (NIH/OD) [E] <(b) (6)@od.nih.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>

Subject: Re: Oracle Platform

Thanks, All.

I am in touch with John Brooks and will connect with Cliff Lane as well.

(b) (5) will be ready for the 5pm deadline.

Take care,

Amy

Amy P. Abernethy, MD PhD
Principal Deputy Commissioner
Acting Chief Information Officer
US Food & Drug Administration

Mobile: 240-429-7034

Email: amy.abernethy@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Saturday, March 21, 2020 6:53 PM

To: Fauci, Anthony S (NIH) <(b) (6) niaid.nih.gov>; Hahn, Stephen <(b) (6) fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; (b) (6) cms.hhs.gov <(b) (6) cms.hhs.gov>

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Joe Grogan <Joseph.J.Grogan@who.eop.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <(b) (6) niaid.nih.gov>; Collins, Francis S (NIH)

<(b) (6) od.nih.gov>

Subject: RE: Oracle Platform

+ Seema

From: Fauci, Anthony (NIH/NIAID) [E] <(b) (6) niaid.nih.gov>

Sent: Saturday, March 21, 2020 6:50 PM

To: Hahn, Stephen <(b) (6) fda.hhs.gov>; Redfield, Robert R (CDC) <olx1@cdc.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Joe Grogan <(b) (6) who.eop.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS) <Seema.Verma@cms.hhs.gov>; Lane, Henry C (NIH) <clane@niaid.nih.gov>; Collins, Francis S (NIH) <collinsf@od.nih.gov>

Subject: RE: Oracle Platform

Steve:

Thanks for the note. Cliff Lane will be my designated person to work with Amy, and if there are other areas of expertise where NIH can contribute such as a person from National Library of Medicine (NLM) and/or the National Center for Advancing Translational Science (NCATS), Cliff will work with me and Dr. Francis Collins (NIH Director) to provide a name and contact information for such a person. I am also copying Dr. Collins on this e-mail.

Best regards,

Tony

From: Hahn, Stephen <(b) (6)@fda.hhs.gov>

Sent: Saturday, March 21, 2020 4:31 PM

To: Redfield, Robert R. (CDC/OD) <olx1@cdc.gov>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)@niaid.nih.gov>; Abernethy, Amy (FDA/OC) <Amy.Abernethy@fda.hhs.gov>

Cc: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Joe Grogan (b) (6)@who.eop.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Verma, Seema (CMS/OA) <Seema.Verma@cms.hhs.gov>

Subject: Oracle Platform

Tony and Bob,

This email is in follow up to our conversation an hour ago regarding the Oracle Platform. I am adding Dr. Amy Abernathy who is the Principle Deputy Commissioner of FDA. CMS Administrator Verma, Joe Grogan, Stacy Amin, Chief Legal Counsel for FDA, and Keagan Lenihan, my Chief of Staff are copied.

We have a 5 pm deadline tomorrow to deliver a plan for (b) (5). Amy will lead this effort and coordinate with your agencies. I know that you will be designating participants to work with Amy. I've downloaded with Amy and she has heard about the details of our conversation earlier today. (b) (5)

The questions are:

1. What are the disclosure, consent, and HIPAA considerations for the platform. We'll need to run the legal traps around this. Stacy, Keagan and I have a call into to you so that we can read you into the details.
2. What are the issues around engagement and communication with the physician community?
3. Do we have the appropriate data fields and who should review them to ensure that we are collecting what we need, balanced with burden on physicians/providers?

The White House had made it clear that they will help us remove any barriers. If you encounter any obstacles, please funnel them to me (cel (b) (6)) and I'll pass them along to the WH. Administrator Verma has agreed to look into any coverage issues that might arise.

Thanks.

Steve

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 8:01:07 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]; (b) (6) who.eop.gov
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)
Start: 3/21/2020 12:30:00 PM
End: 3/21/2020 1:00:00 PM
Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note **updated start time of 12:00 PM**. Thank you.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 3/21/2020 8:01:07 AM
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CC: Rom, Colin [Colin.Rom@fda.hhs.gov]

Subject: Telecon: Coronavirus Treatment Acceleration Program
Location: 1-877-465-7975,,, (b) (6)

Start: 3/21/2020 11:45:00 AM
End: 3/21/2020 12:15:00 PM
Show Time As: Busy

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

Please note updated start time of 11:45 AM. Thank you.

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
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Subject: Telecon: Coronavirus Treatment Acceleration Program
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Show Time As: Tentative

Required Attendees: Keagan Lenihan (Keagan.Lenihan@fda.hhs.gov); Amy Abernethy (Amy.Abernethy@fda.hhs.gov); Shah, Anand; Cavazzoni, Patrizia; Woodcock, Janet; Marks, Peter; (b) (6) who.eop.gov

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
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Please note updated start time of 11:45 AM. Thank you.

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