It's a big news day w debate, COVID, etc.

We'll be prepared to react.
Commissioner, I was exchanging some messages w Heidi on the 21 Forward voices piece.
<table>
<thead>
<tr>
<th>From:</th>
<th>Stephen Hahn</th>
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<tbody>
<tr>
<td>To:</td>
<td>Frank Yiannas</td>
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<tr>
<td>Date:</td>
<td>Tue, 19 Jan 2021 09:07:20 -0500</td>
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Thx
What is the Darian Tarver telecon about?
Checking - Heidi Rebello requested it, confirming with her - but believe his...
From: Frank Olivarria
To: Stephen Hahn
Date: Thu, 19 Nov 2020 12:18:47 -0500

12:30 PM - AMA OWS Vaccine Distribution Briefing for the VP:

(b)(6)
2:00 PM - Birx/Fauci/Redfield/Hahn:

[Tyler Ann has notified that Birx may be delayed in joining the call, please stay on the line for her - she will join as soon as the OWS board meeting wraps]
Birx call is canceled. WHTF was reduced to a small group.

Your next call will be 4 pm with Sen. Scott.
From: Stephen Hahn  
To: Frank Olivarria 
Date: Thu, 19 Nov 2020 14:15:22 -0500

Ok thx
From: Frank Olivarria
To: Stephen Hahn
Date: Thu, 19 Nov 2020 17:00:11 -0500

5:15 PM - Telecon: Vaccine Alignment and Updates:
From: Frank Olivarria
To: Stephen Hahn
Date: Fri, 20 Nov 2020 09:28:20 -0500

9:30 AM - Telecon Check-In: PREPP Initiative:
10:10 AM - Telecon: Birx/Hahn:

Dr. Birx will call your mobile
From: Frank Olivarria messages>
To: Stephen Hahn messages>
Date: Fri, 20 Nov 2020 13:13:28 -0500

1:30 PM - OWS Check-In with the Commissioner and COS:
From: Frank Olivarria
To: Stephen Hahn
Date: Tue, 01 Dec 2020 14:39:17 -0500

3:00 PM - White House Coronavirus Taskforce Meeting:

Watchfloor to call your FDA cell 15 to 10 mins before (approx 2:45/2:50 PM)
Thx
2:30 PM - White House Coronavirus Taskforce Meeting:

Watchfloor to call your FDA cell 15 to 10 mins before (approx 2:15/2:20 PM)
From: Stephen Hahn
To: Frank Olivarria
Date: Mon, 07 Dec 2020 14:12:15 -0500

Thx
3:30 PM - Discussion with Federation of American Hospitals about COVID issues facing hospitals:

Zoom link at the top of your inbox
7:40 PM - Post-VRBPAC Meeting *SH to Join for Final 20 mins*:
+1-210-795-0506
From: Frank Olivarria
To: Stephen Hahn
Date: Thu, 31 Dec 2020 13:30:04 -0500

1:45 PM - Birx/Fauci/Hahn/Redfield:
<table>
<thead>
<tr>
<th>From</th>
<th>Frank Olivarria</th>
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<tbody>
<tr>
<td>To</td>
<td>Stephen Hahn</td>
</tr>
<tr>
<td>Date</td>
<td>Tue, 05 Jan 2021 13:26:56 -0500</td>
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</tbody>
</table>
You will be dropping of this Birx call at 2 pm (early, ends at 2:30) to join CVM - TAM was notified. Then you will drop off the CVM All Hands (your only video of the day) at 2:15 (they are also aware, invite was until 2:30), to join the WHTF at 2:15.
2:15 PM - WHTF:

If the watch floor has not already called to connect you, they can be reached at:

(b)(6)
2021-01-07 15:30:44 UTC: (b)(6) Messages -> (b)(6) Messages}

From: Frank Olivarria messages”>
To: Stephen Hahn messages”>
Date: Thu, 07 Jan 2021 10:30:44 -0500

10:45 AM - Vaccine Distribution Briefing:
1-888-396-9087, (b)(6)
(Materials just came in for this meeting, putting them at the top of your inbox now)
Birx is on - apologies on the delay in the text.
Notified you will be on shortly, Redfield or Fauci are not on.
Sorry, it is not Birx on - it is Seema.
From: Frank Olivarria
To: Stephen Hahn
Date: Tue, 12 Jan 2021 11:45:42 -0500

The WH would like you, or a staff member to dial in 10 mins before the 2 pm Governors call. Nick Alexander will dial in, in advance, and call you at 1:58 pm to connect you to the governors call.

I will text you closer to 2 pm to remind you.
I can call in instead of Nick
Are you able to dial in 10 mins ahead of time? You'll be on a stakeholder call, and if we let Nick dial in first and conference you in, he can listen in (otherwise he cannot).
From: Stephen Hahn
To: Frank Olivarria
Date: Tue, 12 Jan 2021 12:02:48 -0500

Ok for Nick to do so
Copy! Thank you.
From: Frank Olivarria  
To: Stephen Hahn  
Date: Tue, 12 Jan 2021 13:01:12 -0500  

1:15 pm - Discussion with Pediatric Stakeholder Groups on COVID-19 Vaccines & Emergency Use Authorization: 1-888-810-4796
If you have a moment to text me when you hang up the pediatric call, please do and I'll alert Nick - otherwise he will call at 1:58. But he did ask to let us know if you hang up before that.
Liked “If you have a moment to text me when you hang up the pediatric call, please do and I’ll alert Nick - otherwise he will call at 1:58. But he did ask to let us know if you hang up before that.”
| From: | Stephen Hahn | [redacted] messages"|
| To:   | Frank Olivarria | [redacted] messages"|
| Date: | Tue, 12 Jan 2021 13:50:03 -0500 | |

I'm off the pediatric call
Thx
Redfield and Verma were confirmed today, to be dialing in. They should be joining any moment.
<table>
<thead>
<tr>
<th>From:</th>
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<tr>
<td>To:</td>
<td>Stephen Hahn</td>
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<td>Date:</td>
<td>Tue, 19 Jan 2021 13:45:38 -0500</td>
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</tbody>
</table>

WHTF is to begin at 2:00 PM:

WHSR to call your mobile
Yes
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Mon, 22 Jun 2020 18:10:24 -0400

We are moving forward with the EO submission pass back to HHS that is due COB today.

Also, CBER's vaccine guidance has cleared OP and OCC. We are going to flag for Anand in case he wants to look at it before we keep it moving forward to HHS.

Thanks!
Could you show EO to Anand and let me review the vaccine guidance?
Yes on both fronts
From: Stephen Hahn
To: Ann K. Abram, Keagan Lenihan
Date: Mon, 22 Jun 2020 20:13:53 -0400

Tyx
Vaccine guidance now at OIRA, one step closer
Great. Thanks. Did you give Satya a heads up?
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Fri, 26 Jun 2020 12:45:03 -0400

Already done
Thx
Yep
Steve we are putting a quick call together on a timely matter you need to know about
Regarding vaccine guidance
Hold that Peter just said there was a late breaking development negating the need for a call.
Excellent
Just saw this
Thx
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Fri, 26 Jun 2020 17:04:28 -0400
Amazing team effort!
CBD guidance is with HHS now. We hit the timeline of getting it out of FDA by COB today. Thanks!
Liked “CBD guidance is with hhs now. We hit the timeline of getting it out of fda by cob today. Thanks!”
Just got OIRA's comments back on the guidance
The team is following up ASAP
Good news.
Ok to publish tomorrow?
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Mon, 29 Jun 2020 12:00:54 -0400

Won't know until we finish scrubbing the comments
Will update as soon as we have a more definitive read
Ok thx
Just did a quick skim. Looking good. Will keep you posted.
From: Stephen Hahn <messages>
To: Ann K. Abram <messages>, Keagan Lenihan <messages>
Date: Mon, 29 Jun 2020 12:07:04 -0400

Liked “Just did a quick skim. Looking good. Will keep you posted.”
We are a go for posting tomorrow am. Incredible team effort.
From: Stephen Hahn
To: Ann K. Abram, Keagan Lenihan
Date: Mon, 29 Jun 2020 16:12:33 -0400

Liked “We are a go for posting tomorrow am. Incredible team effort.”
Steve, we did a call with Anand and Jeet this morning. Oplia is pulling the regulator country data to hand off to them and CBER/CDER to contextualize. We also gave them related background on the priority work OPLIA is going full steam on. We will continue to advise and comment on what they produce as options accordingly, but really glad they are leading given the clinical significance of this discussion.

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From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Fri, 10 Jul 2020 10:41:48 -0400

EUA vaccine guidance is now back with HHS. Went back this morning.
Thx
From: Stephen Hahn
To: Ann K. Abram, Keagan Lenihan
Date: Sat, 19 Sep 2020 09:28:02 -0400

(b)(5)
Yes.
I will forward you both the passback so you have the latest as well.
From: Keagan Lenihan
To: Stephen Hahn, Ann K. Abram
Date: Sat, 19 Sep 2020 09:34:04 -0400

Thx
Great and thanks
Good news
Bob cleared EUA guidance with our language intact?
That is my understanding.
Yes
I separately confirmed with CBER to make sure we were 100% clear
To:  Ann K. Abram, Keagan Lenihan

Date:  Tue, 22 Sep 2020 08:34:08 -0400

Liked “I separately confirmed with CBER to make sure we were 100% clear”
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Tue, 22 Sep 2020 09:13:26 -0400

This is not the forum for this discussion.
Agreed.

From: Stephen Hahn
To: Ann K. Abram, Keagan Lenihan
Date: Tue, 22 Sep 2020 09:13:50 -0400

Agreed
That was very disheartening to hear about the guidance.
For sure
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Tue, 22 Sep 2020 10:02:22 -0400

Guidance went to: [b]5
From: Stephen Hahn
To: Ann K. Abram, Keagan Lenihan
Date: Tue, 22 Sep 2020 10:04:47 -0400
Because Tony brought up yesterday the issue of
I'm confirming with hhs exec sec
Tony Fauci on the HHS prep call for the Help hearing
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Tue, 22 Sep 2020 10:07:41 -0400

2020-09-22 14:07:41 UTC: Messages -> Messages, Messages
Ok thx
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Tue, 22 Sep 2020 10:10:49 -0400

Peter does a nice job briefing ama
Agreed
It went out more broadly. I am trying to get the distribution list from exec exec. It went to their covid 19 distribution list and I'm trying to get the list of offices on that distribution.
Ok
The distribution was extensive. It went to NIH.
From: Keagan Lenihan
To: Stephen Hahn, Ann K. Abram
Date: Tue, 22 Sep 2020 10:31:30 -0400

Makes me feel a little better.
When should I expect the pager. I'd like to get back to Brad ASAP.
Will check in with Peter now.
He said it will be ready shortly.

From: Keagan Lenihan
To: Stephen Hahn, Ann K. Abram
Date: Thu, 24 Sep 2020 07:44:07 -0400
Sir, Peter outlined what he is pulling together in his morning update. If there is anything else you need pls highlight for him.
That's correct. Call me?
Steve, FDA IGA staff is going to cover the covid tribal consultations. After seeing more details from the dept, this approach is a better fit. Thanks!
From: Ann K. Abram
To: Stephen Hahn, Keagan Lenihan
Date: Tue, 06 Oct 2020 14:13:45 -0400

Guidance is now live
Excellent
Why are we seeing an uptick internally on guidances?
The centers are working on their various items on their respective timelines and they ended up coming forward concurrently, which is consistent with the general ebb and flow on guidances we see, including on COVID.
Ok thx
Steve, I strongly recommend.

Thanks.
Ok let's do that. Can someone ask Anand?
Anna, you go this or need me to check with Anand?
No, IGA is handling. Nick is teaching out to him.
From: Keagan Lenihan
To: Stephen Hahn, Ann K. Abram
Date: Thu, 08 Oct 2020 14:24:27 -0400

Thx
Oops, reaching out to him.
Yes, our FDA IGA team (Nick) is following up with him. Thanks!
Steve, keagan and I connected and I wanted to flag that CBER felt strongly about doing the NGA outreach tomorrow so Peter will now be covering. This is an FDA-NGA dialogue, no hhs or WH involvement. Didn't want you surprised if this came up with Peter. Thanks!
Ok
From: Stephen Hahn
To: Anand Shah, Keagan Lenihan
Date: Fri, 21 Aug 2020 10:17:08 -0400

Henry Walke at CDC is the contact.
Thx. Anand, let's try and get this buttoned up before SH lands. Send the compromise language around before the proposed 5:30 call with Birx.
We will try
Just spoke w cdc Henry and he is going to send me language ASAP to review
Great. Thanks, Anand.
Thx Anand. Appreciate your follow up on this. Were you able to touch base with Brett?
2020-08-21 18:37:45 UTC: (b)(6) Messages -> (b)(6) Messages, (b)(6) Messages

From: Anand Shah
To: Stephen Hahn, Keagan Lenihan
Date: Fri, 21 Aug 2020 14:37:45 -0400

Just spoke with Brett. He is satisfied with where we currently are with FAQ and guidance and feels we have leaned in plenty on this issue. He suggests ___________________________________________. Once I have language from Henry, we will stitch it all together and get it done.
Excellent work. I've spoken to Birx and Giroir. I think we're good but we'll see
From: Stephen Hahn
To: Ann K. Abram, Karas Gross, Maren McBride, Keagan Lenihan
Date: Thu, 25 Jun 2020 13:26:21 -0400

Yes
Great-thanks.
Maren, I'm talking to Dr. Hahn at 9:15 before the call, so I'll patch you in to join us.
Sounds good to me
Do we have a call in?
Full summary of bill, report and markup coming shortly
Thx!
Thank you for flagging. Let's discuss at our next check in as a team.
Hi Dr. Hahn-

I may offer Dr. Shure or Shah first but want to make sure you wouldn’t prefer to do it. Thanks!
Ok either way
Senate R covid bill- doesn't include any funding for FDA. Not a surprise bc I'm told it's just the starting Place For the negotiations of a final package but wanted you to be aware. I'll keep you posted
Thx