

2020-09-27 17:04:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Paul Mango (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 27 Sep 2020 13:04:54 -0400

Steve- can I give you a call late this afternoon? Couple clarification questions about EUA guidance

2020-09-27 17:05:50 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Paul Mango (b)(6) messages">
Date: Sun, 27 Sep 2020 13:05:50 -0400

Sure

2020-09-28 16:51:36 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Paul Mango [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Mon, 28 Sep 2020 12:51:36 -0400

Steve- I had one follow up question whenever you have a minute

2020-09-29 16:10:41 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Paul Mango [REDACTED] (b)(6) messages">
Date: Tue, 29 Sep 2020 12:10:41 -0400

Any follow up?

2020-09-29 16:30:16 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Paul Mango (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 29 Sep 2020 12:30:16 -0400

Still waiting to hear back from Brad. He said heâ€™s on the task though

2020-09-29 16:30:40 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Paul Mango [REDACTED] (b)(6) messages">
Date: Tue, 29 Sep 2020 12:30:40 -0400

Thank you so much

2020-09-29 16:30:45 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Paul Mango (b)(6) messages">
Date: Tue, 29 Sep 2020 12:30:45 -0400

Really appreciate it

2020-10-05 22:38:26 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Jeff Mason [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Mon, 05 Oct 2020 18:38:26 -0400

Hey Steve. Do you know anything about the WH contact tracing (or lack thereof) after the Coney Barrett ceremony? My editors are asking me to match a NYT story about that (it basically says they aren't doing any.) No worries if not. Let's catch up this week if you're free. I'm around.

2020-10-05 22:40:43 UTC: [redacted] (b)(6) **Messages ->**
[redacted] (b)(6) **Messages]**

From: Stephen Hahn [redacted] (b)(6) messages">
To: Jeff Mason [redacted] (b)(6) messages">
Date: Mon, 05 Oct 2020 18:40:43 -0400

I don't know any details of the effort. Would love to catch up

2020-10-05 22:41:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Jeff Mason (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 05 Oct 2020 18:41:55 -0400

Let's do. I'm (b)(6) if you have any windows to chat then.

2020-10-05 23:48:35 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Jeff Mason [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Mon, 05 Oct 2020 19:48:35 -0400

Sorry to bother you with one more story. Can you confirm this on background (ie as an administration official, your name wouldn't be anywhere near it):

(NYT) The F.D.A. proposed stricter guidelines for emergency approval of a coronavirus vaccine, but the White House chief of staff objected to provisions that would push approval past Election Day.

2020-10-05 23:51:10 UTC: [redacted] (b)(6) **Messages ->**
[redacted] (b)(6) **Messages]**

From: Stephen Hahn [redacted] (b)(6) messages">
To: Jeff Mason [redacted] (b)(6) messages">
Date: Mon, 05 Oct 2020 19:51:10 -0400

Can not confirm

2020-12-11 19:22:49 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Jeff Mason [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Fri, 11 Dec 2020 14:22:49 -0500

Hey there. If you feel comfortable confirming the WashPost story that Meadows requested your resignation if approval did not come today, please ping me. Or text Y back. I'll treat it as deep background - ie as a source familiar. No pressure. Sending you positive vibes either way.

2020-11-14 23:01:52 UTC: (b)(6) **Messages ->**
(b)(6) **Messages,** (b)(6) **Messages]**

From: John Redd (b)(6) messages">
To: Rick Scott (b)(6) messages">, Stephen Hahn (b)(6) messages">
Date: Sat, 14 Nov 2020 18:01:52 -0500

Sen. Scott, Dr. Hahn - I just got our distributor on the line. Florida has responded (today!). So FL HAS (late but better than never) accepted 3890 doses.

2020-11-14 23:02:22 UTC: (b)(6) **Messages ->**
(b)(6) **Messages,** (b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Rick Scott (b)(6) messages">, John Redd (b)(6) messages">
Date: Sat, 14 Nov 2020 18:02:22 -0500

Great news. Thx John

2020-11-14 23:03:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages,** (b)(6) **Messages]**

From: John Redd (b)(6) messages">
To: Rick Scott (b)(6) messages">, Stephen Hahn (b)(6) messages">
Date: Sat, 14 Nov 2020 18:03:17 -0500

The first doses to FL will arrive Monday.

2020-11-14 23:48:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages,** (b)(6) **Messages]**

From: Rick Scott (b)(6) messages">
To: John Redd (b)(6) messages">, Stephen Hahn (b)(6) messages">
Date: Sat, 14 Nov 2020 18:48:18 -0500

Thanks

2020-11-21 14:00:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages,** (b)(6) **Messages]**

From: John Redd (b)(6) messages">
To: Rick Scott (b)(6) messages">, Stephen Hahn (b)(6) messages">
Date: Sat, 21 Nov 2020 09:00:31 -0500

Senator (b)(6) please let me know if you need anything.

2020-11-21 15:12:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages,** (b)(6) **Messages]**

From: Rick Scott (b)(6) messages">
To: John Redd (b)(6) messages">, Stephen Hahn (b)(6) messages">
Date: Sat, 21 Nov 2020 10:12:05 -0500

Thanks, (b)(6) Thanks for getting our state the monoclonal antibodies

2020-11-21 21:31:32 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Brett Giroir (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 21 Nov 2020 16:31:32 -0500

(b)(5) I am trying to perturb the system as little as possible. Trust me. But I need some help from CDRH. It has been 4 days and I can't even get a list of those pending (b)(5)
(b)(5) Happy to chat any time

2020-11-22 00:03:09 UTC: [redacted] (b)(6) **Messages ->**
[redacted] (b)(6) **Messages]**

From: Stephen Hahn [redacted] (b)(6) messages">
To: Brett Giroir [redacted] (b)(6) messages">
Date: Sat, 21 Nov 2020 19:03:09 -0500

I'll send you the lists tonight. I had to review them.

2020-11-22 00:03:44 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Brett Giroir [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Sat, 21 Nov 2020 19:03:44 -0500

Perfect. We got enough going on!!!!

2020-11-27 16:43:26 UTC: (b)(6) **Messages -> [3 recipients]**

From: Frank Olivarria (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Stephen Hahn (b)(6) messages">
Date: Fri, 27 Nov 2020 11:43:26 -0500

Noted - thank you.

Will you DNS time on Friday, 12/4?

We will make the day light but you do have two external engagements: 10-11 AM ET (Vaccinate Your Family Conference Call) and 12:45-3:00 PM ET (Zoom: NAM TOWN hall on COVID-19 Vaccine for Health Care Leaders).

2020-12-01 21:24:29 UTC: (b)(6) **Messages -> [3 recipients]**

From: Frank Olivarria (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Stephen Hahn (b)(6) messages">
Date: Tue, 01 Dec 2020 16:24:29 -0500

Commissioner Zucker (NY State Dept of Health) has been asked by Gov. Cuomo to speak with SH today.

Can we coordinate 15 mins with Zucker for today, after 5 pm (since WHTF is running over, we are rescheduling CTP)?

2020-12-01 22:26:39 UTC: (b)(6) **Messages -> [3 recipients]**

From: Frank Olivarria (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Stephen Hahn (b)(6) messages">
Date: Tue, 01 Dec 2020 17:26:39 -0500

Following up on this request ^^^ can we try to schedule for this evening? An alternatively, tomorrow?

2020-12-01 22:26:54 UTC: (b)(6) **Messages -> [3 recipients]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Frank Olivarria (b)(6) messages">
Date: Tue, 01 Dec 2020 17:26:54 -0500

It's taken care of

2020-12-01 22:29:36 UTC: (b)(6) **Messages -> [3 recipients]**

From: Frank Olivarria (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Stephen Hahn (b)(6) messages">
Date: Tue, 01 Dec 2020 17:29:36 -0500

Thank you.

2020-12-01 22:57:29 UTC: (b)(6) **Messages -> [3 recipients]**

From: Frank Olivarria (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Stephen Hahn (b)(6) messages">
Date: Tue, 01 Dec 2020 17:57:29 -0500

Per Dr. Zucker's assistant, Dr. Zucker would like to speak again this evening.

2020-12-01 23:27:53 UTC: (b)(6) **Messages -> [3 recipients]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">, Janice Sheehy (b)(6) messages">,
Frank Olivarria (b)(6) messages">
Date: Tue, 01 Dec 2020 18:27:53 -0500

Done this

2020-04-24 19:15:28 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 24 Apr 2020 15:15:28 -0400

HOLOGIC Panther — they have a pre-EUA. The lead reviewer provided comments last week and they replied to the comments yesterday but they have not yet completed their validation. For Abbott POC, no update since what we sent this morning. We don't expect the EUA until next week.

2020-04-24 20:14:11 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 24 Apr 2020 16:14:11 -0400

Ok. Everything ok?

2020-04-25 12:57:12 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 08:57:12 -0400

You doing TF at HHS today?

2020-04-25 13:44:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 09:44:41 -0400

Absolutely yes

2020-04-25 13:45:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 09:45:19 -0400

Thx.

2020-04-25 19:10:40 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 15:10:40 -0400

I asked Jeff if he has been working with NIOSH as they update and his response: Yes, we have been working with NIOSH. Some of the KN95s that China authorized under their comparable system are failing some of the NIOSH testing which may be due to poor quality controls in their manufacturing. (b)(5)
(b)(5)

2020-04-25 19:31:22 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 15:31:22 -0400

The CoS is going to check in with NIOSH too and make sure they are working with us.

2020-04-25 19:39:24 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 15:39:24 -0400

Ok

2020-04-25 19:54:09 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 15:54:09 -0400

Ok

2020-04-26 01:38:52 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:38:52 -0400

Can we (b)(5)

2020-04-26 01:39:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:39:18 -0400

What?

2020-04-26 01:40:00 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:00 -0400

It's a new news network

2020-04-26 01:40:14 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:14 -0400

Oh. Ok.

2020-04-26 01:40:16 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:16 -0400

John Krasinski

2020-04-26 01:40:23 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:23 -0400

Will talk to real.

2020-04-26 01:40:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:26 -0400

Team

2020-04-26 01:40:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:31 -0400

Love concept

2020-04-26 01:40:37 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:37 -0400

Some Good News = SGN

2020-04-26 01:40:50 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:40:50 -0400

(b)(5)

2020-04-26 01:41:24 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:41:24 -0400

Ok. Will work with team.

2020-04-26 01:41:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:41:33 -0400

Have they really reached out?

2020-04-26 01:42:27 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:42:27 -0400

No I'm watching it now

2020-04-26 01:42:48 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:42:48 -0400

We should do convalescent plasma

2020-04-26 01:43:07 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Sat, 25 Apr 2020 21:43:07 -0400

Oh. Will get team to look into and pitch.

2020-04-26 01:44:12 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 25 Apr 2020 21:44:12 -0400

I asked Colin to DM on Twitter

2020-04-26 01:45:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 25 Apr 2020 21:45:19 -0400

Ok

2020-04-27 12:46:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 27 Apr 2020 08:46:55 -0400

Did you see a email from Dr Birx at 7:53

2020-04-27 12:47:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 27 Apr 2020 08:47:01 -0400

Needs urgent review.

2020-04-27 12:52:07 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 27 Apr 2020 08:52:07 -0400

It's already done

2020-04-27 14:24:06 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 27 Apr 2020 10:24:06 -0400

Brady hasn't gotten back to me. She said she would call after her next meeting.

2020-04-27 14:30:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 27 Apr 2020 10:30:39 -0400

Ok

2020-04-27 14:33:25 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 27 Apr 2020 10:33:25 -0400

Brady just texted. She thinks she just want to talk testing

2020-04-27 14:33:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 27 Apr 2020 10:33:33 -0400

Ok

2020-04-27 17:50:44 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 27 Apr 2020 13:50:44 -0400

Colin sent testing talkers.

2020-04-28 14:30:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 10:30:55 -0400

Sir- no downtime on the itinerary we got from VP office to connect with Dr. Patel. We will let their office know.

2020-04-28 14:32:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 28 Apr 2020 10:32:01 -0400

Ok th

2020-04-28 15:21:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 11:21:13 -0400

Sir, there is another prep for WH meeting tomorrow with AMA at 9:30am. Do you want to (b)(5)
(b)(5)?

2020-04-28 19:32:53 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 15:32:53 -0400

Patrizia is pushing. They all recognize the importance. They are concurrently working on EUA and NDA. But they really haven't seen any data.

2020-04-28 19:33:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 15:33:05 -0400

The good news is the EUA is there so they have something to work off of.

2020-04-28 19:33:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 15:33:31 -0400

Of SNS takes the donation though , it will take time for BARDA to put together and EUA and start from scratch.

2020-04-28 19:45:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 28 Apr 2020 15:45:01 -0400

Ok

2020-04-28 20:53:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 28 Apr 2020 16:53:17 -0400

Can you arrange a call at 7:30 re: remdesivir Azar, Hahn, Amin, Keagan, Charrow, Woodcock and Kadelick?

2020-04-28 21:46:06 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 17:46:06 -0400

EUA from CDER for Remdesivir likely ready Friday, but will let Gilead know they will approve Friday

2020-04-28 21:46:14 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 28 Apr 2020 17:46:14 -0400

Let them know tomorrow.

2020-04-28 22:01:09 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 28 Apr 2020 18:01:09 -0400

Thx

2020-04-30 13:15:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 30 Apr 2020 09:15:39 -0400

You 9:15 is the small group about back to facilities.

2020-04-30 13:15:50 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 30 Apr 2020 09:15:50 -0400

I'm on

2020-04-30 17:36:59 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 30 Apr 2020 13:36:59 -0400

I think we should do a press release on umbrella EUA and first NCI validation.

2020-04-30 17:39:29 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 30 Apr 2020 13:39:29 -0400

(b)(5) I have had evening calls with the Comms team and Anand about this rollout. It's coming together. Will make sure it's simple and understandable.

2020-04-30 17:59:24 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 30 Apr 2020 13:59:24 -0400

Liked (b)(5) I have had evening calls with the Comms team and Anand about this rollout. It's coming together. Will make sure it's simple and understandable. "

2020-04-30 17:59:28 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 30 Apr 2020 13:59:28 -0400

Liked "I think we should do a press release on umbrella EUA and first NCI validation. "

2020-05-01 17:05:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 01 May 2020 13:05:05 -0400

Kennedy was like a dog with a bone on DPA. You handled well.

2020-05-01 17:08:20 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 01 May 2020 13:08:20 -0400

Thx

2020-05-01 21:04:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 01 May 2020 17:04:13 -0400

QIRA is pushing back on (b)(5) I have engaged Joe, but might need your help (b)(5)
(b)(5)

2020-05-02 20:02:21 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 02 May 2020 16:02:21 -0400

Serology policy cleared WH. So no need to (b)(5) Thanks.

2020-05-02 20:22:37 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 02 May 2020 16:22:37 -0400

Great. Can it be sent to me?

2020-05-02 21:11:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 02 May 2020 17:11:19 -0400

Will have Lauren Roth

2020-05-02 21:14:12 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 02 May 2020 17:14:12 -0400

Thx

2020-05-02 21:16:10 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 02 May 2020 17:16:10 -0400

They are cleaning up edits and will send you a clean copy.

2020-05-02 21:16:15 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 02 May 2020 17:16:15 -0400

Thx

2020-05-03 13:22:42 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 03 May 2020 09:22:42 -0400

Sir, I have a serology Comms rollout call at 9:30. Want to chat after to run through calendar?

2020-05-03 13:51:49 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sun, 03 May 2020 09:51:49 -0400

Sorry, I have a 10 am call. Call after that?

2020-05-03 13:55:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 03 May 2020 09:55:31 -0400

Yep

2020-05-03 16:12:20 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 03 May 2020 12:12:20 -0400

Seems to be a big disconnect on allocation and distribution of Remi. (b)(5)
(b)(5) Just emailed Admiral P for info.

2020-05-04 12:37:04 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:37:04 -0400

Still scrambling this am on distribution. Trying to figure it out, (b)(5)

2020-05-04 12:38:12 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 04 May 2020 08:38:12 -0400

Ugh
Why?

2020-05-04 12:38:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:38:54 -0400

No one (b)(5) or has the expertise in house. FEMA and ASPR set up to fail here.

2020-05-04 12:39:04 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:39:04 -0400

Would have been better (b)(5)

2020-05-04 12:39:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 04 May 2020 08:39:31 -0400

Ok

2020-05-04 12:39:46 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Mon, 04 May 2020 08:39:46 -0400

How did you find out about the loose ends?

2020-05-04 12:40:37 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:40:37 -0400

ASPR called me this am. I have been on phone with them and Anand most of the morning. Anand trying to (b)(5)
(b)(5)

2020-05-04 12:41:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 04 May 2020 08:41:41 -0400

Wasn't this always (b)(5)

2020-05-04 12:42:15 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:42:15 -0400

ASPR doesn't have clinical or ethical expertise with this drug or type of therapy. (b)(5)
(b)(5)

2020-05-04 12:42:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:42:33 -0400

Company doesn't want to allocate either. (b)(4)

2020-05-04 12:44:07 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 04 May 2020 08:44:07 -0400

Ok I get it. But we'll also need Deb B's input

2020-05-04 12:44:28 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:44:28 -0400

Exactly

2020-05-04 12:49:37 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 04 May 2020 08:49:37 -0400

Do you (b)(5)

2020-05-04 12:50:43 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:50:43 -0400

Not yet.

2020-05-04 12:51:04 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 08:51:04 -0400

I might (b)(5) Is that ok?

2020-05-04 14:54:34 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Mon, 04 May 2020 10:54:34 -0400

Is the Whitaker/Birx/you call one that should include [REDACTED] (b)(5)

2020-05-04 14:54:49 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 04 May 2020 10:54:49 -0400

Just Scott

2020-05-04 14:55:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 10:55:13 -0400

She will only give us one 15 min window and Scott is requesting Dx. Should I let (b)(5)

2020-05-04 14:55:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 04 May 2020 10:55:30 -0400

Just have the 3 of you on the call?

2020-05-05 18:06:46 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 05 May 2020 14:06:46 -0400

APHL wants to keep the call in hopes you can join.

2020-05-05 18:06:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 05 May 2020 14:06:54 -0400

Jeff will manage if you can't.

2020-05-05 19:04:35 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 05 May 2020 15:04:35 -0400

Abbott test: It was submitted (b)(4) and they did not test enough lay users or collect sufficient
fingersticks: (b)(4)

2020-05-05 23:07:51 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 05 May 2020 19:07:51 -0400

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions#drugs>



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ADMINISTRATION

2020-05-05 23:07:51 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 05 May 2020 19:07:51 -0400

6th question down

2020-05-05 23:10:56 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 05 May 2020 19:10:56 -0400

Thx

2020-05-06 22:40:37 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 06 May 2020 18:40:37 -0400

Admiral P was (b)(5) He confirmed he was ok with that?

2020-05-06 22:40:57 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 06 May 2020 18:40:57 -0400

The department is (b)(5)

2020-05-06 22:41:14 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 06 May 2020 18:41:14 -0400

I sent him the list, if you want to confirm with him from that email feel free.

2020-05-06 22:42:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 06 May 2020 18:42:13 -0400

They want you to call Meadows on it too

2020-05-07 13:34:22 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 07 May 2020 09:34:22 -0400

Reminder- serology call

2020-05-07 14:13:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 07 May 2020 10:13:05 -0400

Ok

2020-05-07 16:49:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 07 May 2020 12:49:17 -0400

1:30 Remdesivir call with Docs and HHS.

2020-05-07 17:29:48 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 07 May 2020 13:29:48 -0400

Yes sir.

2020-05-08 12:08:56 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 08 May 2020 08:08:56 -0400

Didn't make it on agenda, but I think talking about (b)(5) with Hargan is a good idea. His office oversees ASA.

2020-05-08 12:16:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 08 May 2020 08:16:33 -0400

Ok will do. I'm not interested in spending my day at HHS so I'll leave after the SCIF. Maybe we can move up that appointment

2020-05-08 17:41:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 08 May 2020 13:41:54 -0400

(b)(5) (b)(6)

2020-05-08 17:44:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 08 May 2020 13:44:41 -0400

I think so but will ask

2020-05-08 17:50:38 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 08 May 2020 13:50:38 -0400

Thanks.

2020-05-08 19:48:47 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 08 May 2020 15:48:47 -0400

Heidi sending all hands on quarantine to you now.

2020-05-10 21:23:59 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 10 May 2020 17:23:59 -0400

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions#drugs>



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2020-05-11 12:19:53 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 11 May 2020 08:19:53 -0400

Sorry, dropped call. You good?

2020-05-11 12:20:11 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Mon, 11 May 2020 08:20:11 -0400

I am good. You have what you need for HELP?

2020-05-11 13:03:34 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 09:03:34 -0400

Talked to Amy about data and Meadows. She is happy to (b)(5) NYS data being published in JAMA today

2020-05-11 13:03:43 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 11 May 2020 09:03:43 -0400

Liked "I am good. You have what you need for HELP?"

2020-05-11 13:04:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 09:04:05 -0400

Everything she sees (b)(5)

2020-05-11 13:04:08 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 11 May 2020 09:04:08 -0400

For real???? NYS data?

2020-05-11 13:04:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 09:04:26 -0400

Yes. Thatâ€™s what she said. Want a call wit (b)(5)

2020-05-11 13:04:28 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Mon, 11 May 2020 09:04:28 -0400

He wants to know about our efforts on outpatient usage

2020-05-11 13:04:34 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 11 May 2020 09:04:34 -0400

Liked "Yes. That's what she said. Want a call with (b)(5)"

2020-05-11 13:04:57 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 09:04:57 -0400

The folks that did the NYS data also doing outpatient, but she doesn't expect results in the next few days.

2020-05-11 14:54:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 10:54:55 -0400

FYI for your 11am, Gov Hogan has asked for a call with you (we have it scheduled tomorrow). He wants FDA to use our labs for clinical testing. Apparently we aren't set up for this, we aren't CLIA certified (b)(5)
(b)(5)

2020-05-11 18:34:11 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Mon, 11 May 2020 14:34:11 -0400

How many PCR EUAs have been authorized?

2020-05-11 18:34:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 14:34:30 -0400

Let me check

2020-05-11 18:35:57 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 14:35:57 -0400

79 pcr (commercial and ldt). 12 serology. 1 antigen.

2020-05-11 18:47:13 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 14:47:13 -0400

Do you want to discuss (b)(5)

2020-05-11 19:10:16 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 11 May 2020 15:10:16 -0400

Do we need to flag the fact (b)(5) ?

2020-05-11 19:19:21 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Mon, 11 May 2020 15:19:21 -0400

Probably although we weren't involved in the decision

2020-05-12 17:11:25 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 12 May 2020 13:11:25 -0400

Hearing a bit brutal today

2020-05-12 17:23:53 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 13:23:53 -0400

Yep.

2020-05-12 17:25:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 12 May 2020 13:25:39 -0400

What is the agenda item 'coronavirus?'

2020-05-12 17:26:38 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 13:26:38 -0400

I think PM is suppose to give vaccine update, Jim on inspections and Roundtable.

2020-05-12 17:26:48 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 13:26:48 -0400

Not sure what Coronavirus is.

2020-05-12 17:27:14 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 13:27:14 -0400

What do you need?

2020-05-12 17:27:34 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 12 May 2020 13:27:34 -0400

Yes I'm good for WHTF

2020-05-12 17:27:46 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 13:27:46 -0400

Ok. Thanks. Is JW joining?

2020-05-12 17:27:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 12 May 2020 13:27:54 -0400

No

2020-05-12 18:10:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 14:10:41 -0400

WHTF got moved to 3pm

2020-05-12 18:24:27 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 14:24:27 -0400

Your background at the hearing was trending on Twitter today. Very "heavenly". Pretty funny.

2020-05-12 20:32:45 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 16:32:45 -0400

Still on? You have Mayo CEO call at 4:45

2020-05-12 20:33:23 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 16:33:23 -0400

He just wants to provide you an update about a Thermo Fisher announcement

2020-05-12 20:34:51 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 12 May 2020 16:34:51 -0400

I can move it if you need me to

2020-05-13 19:31:22 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 13 May 2020 15:31:22 -0400

(b)(5)

2020-05-13 19:31:52 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Wed, 13 May 2020 15:31:52 -0400

After WHTF they want to do a quick prep call and then have you speak with reporter.

2020-05-13 20:12:20 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 13 May 2020 16:12:20 -0400

FDA issued an EUA for these specific drugs: (b)(3), (b)(5)

(b)(3), (b)(5)

During the evaluation of the criteria under which to issue an EUA, it was determined, based on the scientific evidence available, that it is reasonable to believe that the specific drugs may be effective in treating COVID-19, and that, given there are no adequate, approved, or available alternative treatments, the known and potential benefits to treat this serious or life-threatening virus outweigh the known and potential risks when used under the conditions described in the EUA. Those conditions include use when a clinical trial is not available or feasible, as well as reporting requirements for administration under emergency use authorization. The EUA also requires that fact sheets that provide important information about using these drugs in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions.

2020-05-13 20:19:09 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 13 May 2020 16:19:09 -0400

Let me know when you can chat with them.

2020-05-13 21:40:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 13 May 2020 17:40:54 -0400

Do you want call with Mark from TF this week?

2020-05-13 22:08:58 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 13 May 2020 18:08:58 -0400

Yes please

2020-05-14 15:27:52 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 14 May 2020 11:27:52 -0400

Do you know what the 5 pm meeting is about?

2020-05-14 15:28:35 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 14 May 2020 11:28:35 -0400

Let me check

2020-05-14 16:26:11 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Thu, 14 May 2020 12:26:11 -0400

For 5pm call:
Dr. Disbrow was asked to convene this group to present the plan for the [REDACTED] (b)(4), (b)(5)
candidate. Slide will be coming shortly.

2020-05-14 16:40:28 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Thu, 14 May 2020 12:40:28 -0400

Ok thx

2020-05-14 20:03:45 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 14 May 2020 16:03:45 -0400

Joining the 4?

2020-05-14 20:04:00 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 14 May 2020 16:04:00 -0400

With Mark from Thermo Fisher?

2020-05-14 22:16:57 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 14 May 2020 18:16:57 -0400

Can you hold on the (b)(5) please?

2020-05-14 22:23:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 14 May 2020 18:23:19 -0400

Yes. Heard from Judy.

2020-05-15 00:04:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 14 May 2020 20:04:05 -0400

So you can just walk in and get tested? Don't need an appointment?

2020-05-15 00:41:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 14 May 2020 20:41:05 -0400

Peter and JW are all set for tomorrow and will be there.

2020-05-15 10:24:53 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 15 May 2020 06:24:53 -0400

Multiple questions about (b)(5)

2020-05-15 10:25:16 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 15 May 2020 06:25:16 -0400

Ok. Thx.

2020-05-15 10:35:56 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 15 May 2020 06:35:56 -0400

On (b)(5) Got it.

2020-05-15 10:39:37 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 15 May 2020 06:39:37 -0400

And how it could be used by WH

2020-05-15 13:16:12 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 15 May 2020 09:16:12 -0400

Just calling you about Abbott test. AMA has questions

2020-05-16 12:19:25 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Sat, 16 May 2020 08:19:25 -0400

Do you have access to the NIOSH list for masks?

2020-05-16 12:58:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 08:58:41 -0400

I don't think so, but can ask.

2020-05-16 13:00:09 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Sat, 16 May 2020 09:00:09 -0400

Didn't you pass it along to FEMA?

2020-05-16 13:00:47 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:00:47 -0400

Sent them what we were pulling II think. Let me look. Will send shortly.

2020-05-16 13:00:59 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 16 May 2020 09:00:59 -0400

That's what I meant, sorry

2020-05-16 13:01:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:01:18 -0400

Gotcha. Hold one sec

2020-05-16 13:01:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 16 May 2020 09:01:26 -0400

Looking for a company called (b)(4)

2020-05-16 13:03:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:03:39 -0400

Just emailed you list. Didn't see it on there. Let me look for NIOSH and non NIOSH approved masks

2020-05-16 13:04:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 16 May 2020 09:04:05 -0400

From meadows to Alex

2020-05-16 13:04:11 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:04:11 -0400

Ok

2020-05-16 13:06:35 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:06:35 -0400

Let me check with Suzanne.

2020-05-16 13:22:44 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:22:44 -0400

Just forwarded you email from Suzanne. She said she downloaded with Jeff so guessing he will call you too.

2020-05-16 13:22:53 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 16 May 2020 09:22:53 -0400

Thx

2020-05-16 13:52:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

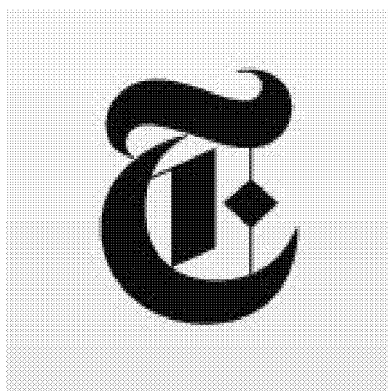
From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 09:52:31 -0400

Emails in your inbox (b)(4)
Suzanne team pulling together review today.

2020-05-16 18:20:21 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 14:20:21 -0400

<https://www.nytimes.com/2020/05/15/us/coronavirus-testing-seattle-bill-gates.html>





2020-05-16 18:20:21 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 14:20:21 -0400

Here is the story, working on getting you talkers.

2020-05-16 18:20:39 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Sat, 16 May 2020 14:20:39 -0400

OMA has been on the phone with the HHS press team working on prep materials for AMA.

2020-05-16 18:23:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 16 May 2020 14:23:30 -0400

Ok. We still have the underlying issue to deal with

2020-05-16 18:23:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sat, 16 May 2020 14:23:39 -0400

Yep

2020-05-16 18:24:08 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sat, 16 May 2020 14:24:08 -0400

Can you put that issue on the agenda of our next call together?

2020-05-18 14:49:16 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 10:49:16 -0400

Fred Turner, CEO of Curative cell# (b)(6)

2020-05-18 14:49:34 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 10:49:34 -0400

I spoke with Jeff and we agree (b)(5)

2020-05-18 14:50:59 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 10:50:59 -0400

You should call and say (b)(5)
(b)(5) They should expect to here from CDRH today.

2020-05-18 18:43:43 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 14:43:43 -0400

Sorry this took a while.

Henry Ji, PhD
Chairman, President and Chief Executive Officer
Sorrento Therapeutics
E-mail: Hji@sorrentotherapeutics.com
Cell Phone: (b)(6)

2020-05-18 18:44:08 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 14:44:08 -0400

Do you want us to set up a call or just direct dial him yourself?

2020-05-18 18:46:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 18 May 2020 14:46:26 -0400

I'll call

2020-05-18 18:46:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 14:46:30 -0400

Ok

2020-05-18 20:37:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 18 May 2020 16:37:13 -0400

Anand said he just sent you a note on HCQ Comms

2020-05-18 20:37:56 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 18 May 2020 16:37:56 -0400

Ok

2020-05-19 13:40:40 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 09:40:40 -0400

Howard Zucker called the front office line for you. Can you give him a call after CD call? (b)(6)

2020-05-19 13:40:48 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 09:40:48 -0400

Yes

2020-05-19 13:40:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 09:40:54 -0400

Thx

2020-05-19 14:29:46 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 19 May 2020 10:29:46 -0400

How about for AEG: MWF with Wednesday being at 4 pm?

2020-05-19 14:31:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 10:31:26 -0400

Works for me. Any concerns with WHTF?

2020-05-19 14:31:51 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 19 May 2020 10:31:51 -0400

No

2020-05-19 14:31:58 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 10:31:58 -0400

I will talk to Denise.

2020-05-19 14:32:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 19 May 2020 10:32:31 -0400

We can't continue to be held hostage by the lack of clarity

2020-05-19 14:32:51 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 10:32:51 -0400

Totally agree.

2020-05-19 17:02:53 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:02:53 -0400

Ok

2020-05-19 17:07:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 13:07:30 -0400

FYI- Brian Harrison, VADM Daniel Abel, CAPT Michael Barton have requested meeting with you and I at 4pm. Will try and get a little info about what it is. Is 4pm ok with you?

2020-05-19 17:17:28 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:17:28 -0400

Depends on the topic

2020-05-19 17:19:11 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:19:11 -0400

Who are Abel and Barton?

2020-05-19 17:20:14 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:20:14 -0400

New people that are a part of the OWS project. I think it's probably an intro call to read us in on how things will operate, but getting more info.

2020-05-19 17:20:24 UTC: [redacted] (b)(6) **Messages ->**
[redacted] (b)(6) **Messages]**

From: Keagan Lenihan [redacted] (b)(6) messages">
To: Stephen Hahn [redacted] (b)(6) messages">
Date: Tue, 19 May 2020 13:20:24 -0400

Think they are from DoD

2020-05-19 17:20:33 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:20:33 -0400

Oh ok, that's fine

2020-05-19 17:20:38 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 13:20:38 -0400

Ok

2020-05-19 17:39:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 13:39:33 -0400

Oh, perfect. Thx.

2020-05-19 17:45:19 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:45:19 -0400

Looks like the Harrison call is tomorrow at 4

2020-05-19 17:48:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 13:48:55 -0400

Yes. They moved to to tomorrow.

2020-05-19 17:50:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 19 May 2020 13:50:18 -0400

Liked œYes. They moved to to tomorrow.œ

2020-05-19 17:57:07 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 13:57:07 -0400

Paul said the call tomorrow is an Introduction to VADM Abel who will be helping us coordinate internal COVID response as we transition activities back to HHS. We are introducing him to all key COVID related operating divisions. Doing the same with NIH, CDC, ASPR, CMS. He will not be working on OWS. Sounds like a project manager to coordinate HHS wide efforts on COVID.

2020-05-19 17:59:56 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 19 May 2020 13:59:56 -0400

Great

2020-05-19 18:15:54 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 14:15:54 -0400

We have Brian Harrison tomorrow during the time we were going to move AEG and you have AMA meeting at 5.

2020-05-19 21:16:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 17:16:55 -0400

Shook loose MOU. Moving forward.

2020-05-19 21:18:34 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 19 May 2020 17:18:34 -0400

Excellent. You are terrific

2020-05-19 21:18:56 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 19 May 2020 17:18:56 -0400

Team effort. Thx.

2020-05-19 21:19:04 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 19 May 2020 17:19:04 -0400

Great

2020-05-20 14:48:59 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 20 May 2020 10:48:59 -0400

Did you get in touch with Henry from Sorrento? Or did you want us to set up a call.

2020-05-20 18:51:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 20 May 2020 14:51:01 -0400

Also, Jeff just sent list of serology tests coming off to your email (b)(5)

2020-05-22 14:24:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 10:24:30 -0400

Bill gates meeting: the request is to discuss vaccine development, as well as data around both vaccines and therapeutics.

2020-05-22 14:24:40 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 10:24:40 -0400

Do you want me to (b)(5)

2020-05-22 14:24:48 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 22 May 2020 10:24:48 -0400

YES PLEASE

2020-05-22 14:24:52 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 10:24:52 -0400

Will do.

2020-05-22 16:54:16 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 12:54:16 -0400

Looks like (b)(5)

2020-05-22 17:00:49 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 22 May 2020 13:00:49 -0400

Ok

2020-05-22 17:03:58 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 13:03:58 -0400

Stacy was (b)(5) Do you need anything since the discussion is vaccines and therapeutics.
Do you want (b)(5)

2020-05-22 17:04:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 13:04:41 -0400

Apparently, the call he had with the Dept about testing he wasn't very pleasant.

2020-05-22 17:06:12 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 22 May 2020 13:06:12 -0400

I'll do it alone. They don't need the hassle

2020-05-22 17:13:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 13:13:13 -0400

Ok.

2020-05-22 17:47:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 22 May 2020 13:47:41 -0400

Sir, the 3pm is follow up with OCC and Anand on (b)(5) and also Stacy and Anand need to discuss some (b)(5)

2020-05-25 16:15:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 25 May 2020 12:15:01 -0400

Back to offices update?

2020-05-25 16:15:07 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 25 May 2020 12:15:07 -0400

Sounds good.

2020-05-25 16:19:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 25 May 2020 12:19:26 -0400

WHTF likely to be Tuesday and Thursday. Can we move

(b)(5)

2020-05-25 16:19:45 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 25 May 2020 12:19:45 -0400

Will ask Janice.

2020-05-25 16:20:06 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 25 May 2020 12:20:06 -0400

Thx

2020-05-27 16:59:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 27 May 2020 12:59:19 -0400

FYI- JW sounds like she is really struggling with OWS. Seems like it's a cluster.

2020-05-27 17:09:06 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Wed, 27 May 2020 13:09:06 -0400

You wanted to do Gates call solo, right?

[REDACTED] (b)(5)

2020-05-27 17:09:19 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Wed, 27 May 2020 13:09:19 -0400

Right

2020-05-27 17:09:45 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 27 May 2020 13:09:45 -0400

Thx

2020-05-27 17:10:00 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 27 May 2020 13:10:00 -0400

When is it?

2020-05-27 17:10:06 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 27 May 2020 13:10:06 -0400

Tomorrow

2020-05-28 00:27:29 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 27 May 2020 20:27:29 -0400

Yes for Gates. (b)(5)

2020-05-28 00:32:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 27 May 2020 20:32:01 -0400

Thx

2020-05-28 23:32:04 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 28 May 2020 19:32:04 -0400

Jeff called on (b)(4) Did you connect? If not, happy to chat.

2020-05-29 00:45:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 28 May 2020 20:45:18 -0400

Jeff and (b)(4)?

2020-05-29 00:46:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 28 May 2020 20:46:18 -0400

Ha. Right (b)(4)
(b)(4) Can't make this up.

2020-05-29 00:46:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 28 May 2020 20:46:55 -0400

Seriously?

2020-05-29 00:47:12 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 28 May 2020 20:47:12 -0400

Laughed at "Ha. Right (b)(4)
(b)(4) Can't make this up. "

2020-05-29 00:47:18 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 28 May 2020 20:47:18 -0400

Yep. He (b)(5) to have a response.

2020-05-29 00:47:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 28 May 2020 20:47:33 -0400

Ok let's talk with n AM

2020-05-29 00:47:40 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 28 May 2020 20:47:40 -0400

I am going to get CDRH, OP and OCC together to discuss. And get back to you

2020-05-29 00:48:00 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 28 May 2020 20:48:00 -0400

Happy to discuss tomorrow.

2020-05-29 13:44:50 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 29 May 2020 09:44:50 -0400

Feedback session right

2020-05-29 13:45:06 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 29 May 2020 09:45:06 -0400

That is my understanding. Anything you need?

2020-05-29 13:45:06 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Fri, 29 May 2020 09:45:06 -0400

No specific agenda, right?

2020-05-29 13:45:14 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 29 May 2020 09:45:14 -0400

Will send what I have.

2020-05-29 13:45:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Fri, 29 May 2020 09:45:17 -0400

Nope just want to understand

2020-05-29 13:49:06 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Fri, 29 May 2020 09:49:06 -0400

Memorandum

To: Dr. Hahn
From: OEA Stakeholder Team
Re: PhRMA CEO call re COVID-19 Vaccines on Friday, May 29th, 2020

Below please find your talking points and the agenda items PhRMA would like to discuss during the call tomorrow. Also, BIO may have a few attendees as well, but we are still waiting on confirmation from them.

Joining you for this call from FDA:
Dr. Peter Marks, Director, CBER

(b)(5)

Agenda

Welcome/Opening Remarks	Commissioner Stephen Hahn Dr. Peter Marks
Summary Industry Updates	Vas Narasimhan/Novartis/PhRMA
Topics for Discussion:	Vas Narasimhan/Novartis (moderator)

1. Globalization and harmonization of clinical development and regulatory review
2. Risk-based regulatory guidance and expectations for GMP issues associated with vaccine manufacturing

3. Criteria for and timing of inclusion of pediatric subjects in coronavirus vaccine clinical studies

Opening Remarks

Stephen Hahn, FDA Commissioner

(b)(5)

(b)(5)

2020-06-01 18:56:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 01 Jun 2020 14:56:39 -0400

Isnâ€™t that DoDs role in all this?

2020-06-01 18:56:45 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Mon, 01 Jun 2020 14:56:45 -0400

Yes

2020-06-01 18:56:46 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 01 Jun 2020 14:56:46 -0400

Project management and leadership

2020-06-01 18:57:11 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 01 Jun 2020 14:57:11 -0400

Helpful context for your call with the general

2020-06-01 18:57:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Mon, 01 Jun 2020 14:57:19 -0400

Liked "Helpful context for your call with the general"

2020-06-02 12:55:45 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 02 Jun 2020 08:55:45 -0400

And add to CDRH agenda: development of (b)(5)

2020-06-02 12:56:48 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 08:56:48 -0400

Will do.

2020-06-02 12:58:23 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 02 Jun 2020 08:58:23 -0400

Thx

2020-06-02 16:30:38 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Tue, 02 Jun 2020 12:30:38 -0400

Apparently it wasn't leaked docs, it was a FOIA response for the decision memo on hydroxychloroquine EUA. Reporters didn't reach out. Michael is sending to you now.

2020-06-02 16:35:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 12:35:19 -0400

Joining recovery and review?

2020-06-02 20:07:58 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 02 Jun 2020 16:07:58 -0400

Nuclein (b)(4)

2020-06-02 23:28:22 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 19:28:22 -0400

Yep. I emailed OP about (b)(5) Sounds like Anand is working similar

2020-06-02 23:29:41 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 02 Jun 2020 19:29:41 -0400

Jeff and I need to lay eyes on it

2020-06-02 23:29:51 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 19:29:51 -0400

Ok.

2020-06-02 23:29:58 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 19:29:58 -0400

It's with Jeff. He is asking for more time.

2020-06-02 23:30:05 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 19:30:05 -0400

I just asked HHS for more time.

2020-06-02 23:31:45 UTC: [redacted] (b)(6) **Messages ->**
[redacted] (b)(6) **Messages]**

From: Stephen Hahn [redacted] (b)(6) messages">
To: Keagan Lenihan [redacted] (b)(6) messages">
Date: Tue, 02 Jun 2020 19:31:45 -0400

Yes, give him the time he needs

2020-06-02 23:32:01 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 02 Jun 2020 19:32:01 -0400

Deb Birx is aware of our review

2020-06-02 23:32:13 UTC: [redacted] (b)(6) **Messages ->**
[redacted] (b)(6) **Messages]**

From: Keagan Lenihan [redacted] (b)(6) messages">
To: Stephen Hahn [redacted] (b)(6) messages">
Date: Tue, 02 Jun 2020 19:32:13 -0400

Ok. Pushing. Will [redacted] (b)(5)

2020-06-03 01:51:44 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 02 Jun 2020 21:51:44 -0400

Got Jeff till 2pm tomorrow, which he said ok to. Pls provide your feedback before 2 if you can. Thanks.

2020-06-03 13:02:43 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Wed, 03 Jun 2020 09:02:43 -0400

Wow, the Secretary this AM. I'm concerned he's on fire

2020-06-03 13:03:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 09:03:17 -0400

Uh oh. On testing?

2020-06-03 13:04:19 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 03 Jun 2020 09:04:19 -0400

In general. He's trying to reassert control but has trouble treating all of us adults

2020-06-03 13:04:48 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 09:04:48 -0400

Not helpful

2020-06-03 14:28:09 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 10:28:09 -0400

Anything else you want to discuss?

2020-06-03 14:28:31 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 03 Jun 2020 10:28:31 -0400

Back to office update?

2020-06-03 15:24:44 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 11:24:44 -0400

Just to double check, with yours and Jeff's edits to the document we are ok to concur with this document?

2020-06-03 15:25:10 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 03 Jun 2020 11:25:10 -0400

I am just double check with Jeff

2020-06-03 15:29:46 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 11:29:46 -0400

Ok

2020-06-03 15:53:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 11:53:01 -0400

Did he get back to you?

2020-06-03 15:53:07 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 11:53:07 -0400

I have to let them know by noon.

2020-06-03 15:53:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 03 Jun 2020 11:53:55 -0400

He sent me his comments but didn't answer the concur question. Can you query him?

2020-06-03 15:54:03 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Wed, 03 Jun 2020 11:54:03 -0400

Yes

2020-06-03 16:00:01 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 12:00:01 -0400

From Jeff- Fine to send my comments. Consider them technical comments. (b)(5)

(b)(5)

2020-06-03 16:00:24 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 03 Jun 2020 12:00:24 -0400

Do you concur?

2020-06-03 16:00:43 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Wed, 03 Jun 2020 12:00:43 -0400

Concur

2020-06-03 16:01:01 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Wed, 03 Jun 2020 12:01:01 -0400

Thx

2020-06-04 13:09:12 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 04 Jun 2020 09:09:12 -0400

Do you want to chat vaccine email with Anand and I now?

2020-06-04 16:53:15 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 04 Jun 2020 12:53:15 -0400

Any quick updates at beginning of CD call today? Maybe mentioning (b)(5)
(b)(5)

2020-06-04 16:59:35 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Thu, 04 Jun 2020 12:59:35 -0400

I think I'll hold off on [REDACTED] (b)(5)

2020-06-04 16:59:42 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 04 Jun 2020 12:59:42 -0400

Ok

2020-06-08 14:30:13 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 08 Jun 2020 10:30:13 -0400

Curious how much HCQ ASPR still has under the EUA. I will check.

2020-06-08 19:02:17 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Mon, 08 Jun 2020 15:02:17 -0400

It was a good call until we started talking about HQ

2020-06-08 19:02:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 08 Jun 2020 15:02:39 -0400

Uh oh.

2020-06-08 19:38:55 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Mon, 08 Jun 2020 15:38:55 -0400

Finalizing current rule and working like crazy on COVID

2020-06-09 12:25:10 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 09 Jun 2020 08:25:10 -0400

Any update on the CDC guidance?

2020-06-09 12:25:33 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 08:25:33 -0400

Lowell and Lauren didn't know what it was. Have an email into CDRH.

2020-06-09 12:36:51 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Tue, 09 Jun 2020 08:36:51 -0400

How is that possible? We need to get Anand and Anna on the phone and figure out this guidance clearance process. It seems very disjointed

2020-06-09 12:37:30 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 08:37:30 -0400

Will call Anna.

2020-06-09 12:41:27 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Tue, 09 Jun 2020 08:41:27 -0400

Anna didn't know and hasn't seen. I am calling Anand now.

2020-06-09 12:41:39 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Keagan Lenihan [REDACTED] (b)(6) messages">
To: Stephen Hahn [REDACTED] (b)(6) messages">
Date: Tue, 09 Jun 2020 08:41:39 -0400

Will set up a call for us to work through fixing on our end.

2020-06-09 12:43:53 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 08:43:53 -0400

Anand might know what it is, he says he had issues with CDRH on a CDC guidance Friday. Can you get me the title and he can take care of it.

2020-06-09 12:44:39 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 09 Jun 2020 08:44:39 -0400

Testing guidance

2020-06-09 12:47:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 08:47:17 -0400

It's not for farm workers is it?

2020-06-09 12:55:16 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 09 Jun 2020 08:55:16 -0400

No

2020-06-09 12:56:46 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 08:56:46 -0400

From Tim Stenzel:
Not sure if this is about reporting results of (b)(5) testing. Anyway (b)(5)
(b)(5)

2020-06-09 12:56:57 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 08:56:57 -0400

No one seems to know what the specific guidance is.

2020-06-09 13:40:00 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 09 Jun 2020 09:40:00 -0400

The data are unlikely to be perfect ever

2020-06-09 13:50:10 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 09:50:10 -0400

Right. And every state is going to be different. Seems like almost impossible to track.

2020-06-09 15:36:49 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Tue, 09 Jun 2020 11:36:49 -0400

We should be good on CDC guidance now. CDRH is good with language CMS just sent.

2020-06-09 15:55:17 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Tue, 09 Jun 2020 11:55:17 -0400

Liked "We should be good on CDC guidance now. CDRH is good with language CMS just sent. "

2020-06-10 17:04:11 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 10 Jun 2020 13:04:11 -0400

You can give AMA a heads up on Remdesivir and CQ. Just got the all clear from Patrizia. Likely Friday.

2020-06-10 17:05:23 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Wed, 10 Jun 2020 13:05:23 -0400

Patrizia sent us an explanation email. Make sure you tell him it's CCI.

2020-06-11 14:46:13 UTC: (b)(6) Messages ->

(b)(6) Messages]

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 11 Jun 2020 10:46:13 -0400

I am on the call. Patrizia and Center are comfortable (b)(5)
(b)(5)

2020-06-11 14:54:38 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 11 Jun 2020 10:54:38 -0400

These Comms calls are super strange.

2020-06-11 16:23:15 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Thu, 11 Jun 2020 12:23:15 -0400

It's the same time as the JW plasma call, but to your point earlier you probably don't need to join.

2020-06-11 16:23:26 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Thu, 11 Jun 2020 12:23:26 -0400

Liked "It's the same time as the JW plasma call, but to your point earlier you probably don't need to join. "

2020-06-14 11:41:13 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sun, 14 Jun 2020 07:41:13 -0400

I'm sorry to bother you but I'm going to need your help with this

Peter
I received the following from Congressman McCaul this evening. I don't at all want to prejudge the outcome. I think they just need clarity. Could you reach out to the company? I'll also arrange a call for the 2 of us with the congressman.
Thx

scd.2020.0080.pdf

Dr. Hahn, Michael McCaul here, please see the published periodical. I would like to discuss this with you as soon as possible. We need to move this it's been two weeks and people are dying. We know this is safe and works! Call me at (b)(6) thanks!

(b)(4)

(b)(4) I was told this is a "new FDA" and not the old bureaucratic one. I am concerned by the lack of urgency demonstrated by your staff given the tremendous loss of life during this pandemic. (b)(4)

(b)(4)

(b)(4) I have been very patient and worked on this matter as appropriate under your guidance but if I do not hear from you or your staff in the near future I will have no other choice but to raise this issue to a higher level. The WH is aware of (b)(4)

(b)(4) Thank you for your attention to this matter and I look forward to hearing from you in the near future.

Sincerely,

Michael McCaul

2020-06-14 11:43:51 UTC: (b)(6) Messages ->
(b)(6) Messages]

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 14 Jun 2020 07:43:51 -0400

Do you know the product name?

2020-06-14 11:46:12 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 14 Jun 2020 07:46:12 -0400

I am sure Colin will remember. Let me touch base with him and Karas and i will get back to you.

2020-06-14 11:49:13 UTC: [REDACTED] (b)(6) **Messages ->**
[REDACTED] (b)(6) **Messages]**

From: Stephen Hahn [REDACTED] (b)(6) messages">
To: Keagan Lenihan [REDACTED] (b)(6) messages">
Date: Sun, 14 Jun 2020 07:49:13 -0400

Thank you

2020-06-14 11:49:52 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sun, 14 Jun 2020 07:49:52 -0400

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

2020-06-14 14:25:22 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sun, 14 Jun 2020 10:25:22 -0400

I'll respond

2020-06-14 14:27:35 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 14 Jun 2020 10:27:35 -0400

Thx

2020-06-14 14:38:40 UTC: (b)(6) Messages ->

(b)(6) Messages]

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sun, 14 Jun 2020 10:38:40 -0400

Congressman

I do have follow up for you and have learned that (b)(4)

(b)(4)

(b)(4)

Please let me know

how you would like to proceed.

Steve

2020-06-14 14:38:56 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Stephen Hahn (b)(6) messages">
To: Keagan Lenihan (b)(6) messages">
Date: Sun, 14 Jun 2020 10:38:56 -0400

We need to (b)(5)

2020-06-14 14:39:21 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 14 Jun 2020 10:39:21 -0400

Yes sir

2020-06-14 14:45:00 UTC: (b)(6) **Messages ->**
(b)(6) **Messages]**

From: Keagan Lenihan (b)(6) messages">
To: Stephen Hahn (b)(6) messages">
Date: Sun, 14 Jun 2020 10:45:00 -0400

Ok. Can we chat for 2 mins on EUA?