From: Paul Mango
To: Stephen Hahn
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
Sure
Steve- I had one follow up question whenever you have a minute
Any follow up?
Still waiting to hear back from Brad. He said he’s on the task though
Thank you so much
Really appreciate it.
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.
I don’t know any details of the effort. Would love to catch up
Let's do. I'm if you have any windows to chat then.
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.
From: Stephen Hahn
To: Jeff Mason
Date: Mon, 05 Oct 2020 19:51:10 -0400

Can not confirm
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.
From: John Redd
To: Rick Scott, Stephen Hahn
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.
Great news. Thx John
The first doses to FL will arrive Monday.
Thanks
From: John Redd
To: Rick Scott, Stephen Hahn
Date: Sat, 21 Nov 2020 09:00:31 -0500

Senator (b)(6) anything. (b)(6) please let me know if you need
Thanks, (b)(6) Thanks for getting our state the monoclonal antibodies
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. Happy to chat any time.
I'll send you the lists tonight. I had to review them.
Perfect. We got enough going on!!!!
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).
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)?
Following up on this request ^^^ can we try to schedule for this evening? An alternatively, tomorrow?
It's taken care of
Thank you.
Per Dr. Zucker’s assistant, Dr. Zucker would like to speak again this evening.
Done this
From: Keagan Lenihan
To: Stephen Hahn
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.
Ok. Everything ok?
You doing TF at HHS today?
Absolutely yes
From: Keagan Lenihan
To: Stephen Hahn
Date: Sat, 25 Apr 2020 09:45:19 -0400

Thx.
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.
The CoS is going to check in with NIOSH too and make sure they are working with us.
Ok
From: Stephen Hahn
To: Keagan Lenihan
Date: Sat, 25 Apr 2020 21:38:52 -0400

Can we...
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<tr>
<td>To</td>
<td>Stephen Hahn</td>
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<tr>
<td>Date</td>
<td>Sat, 25 Apr 2020 21:39:18 -0400</td>
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What?
It's a new news network
Oh. Ok.
From: Stephen Hahn
To: Keagan Lenihan
Date: Sat, 25 Apr 2020 21:40:16 -0400

John Krasinski
Will talk to real.
From: Keagan Lenihan
To: Stephen Hahn
Date: Sat, 25 Apr 2020 21:40:26 -0400
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Love concept
Some Good News = SGN
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<td>Sat, 25 Apr 2020 21:40:50 -0400</td>
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Ok. Will work with team.
Have they really reached out?
No I'm watching it now
We should do convalescent plasma
Oh. Will get team to look into and pitch.
I asked Colin to DM on Twitter
Ok
Did you see an email from Dr Birx at 7:53?
Needs urgent review.
It's already done
Brady hasn’t gotten back to me. She said she would call after her next meeting.
Ok
Brady just texted. She thinks she just want to talk testing
Ok
Colin sent testing talkers.
Sir- no downtime on the itinerary we got from VP office to connect with Dr. Patel. We will let their office know.
Ok th
From: Keagan Lenihan
To: Stephen Hahn
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?
Patrizia is pushing. They all recognize the importance. They are concurrently working on EUA and NDA. But they really haven’t seen any data.
The good news is the EUA is there so they have something to work off of.
Of SNS takes the donation though, it will take time for BARDA to put together and EUA and start from scratch.
Ok
Can you arrange a call at 7:30 re: remdesivir Azar, Hahn, Amin, Keagan, Charrow, Woodcock and Kadelick?
EUA from CDER for Remdesivir likely ready Friday, but will let Gilead know they will approve Friday.
Let them know tomorrow.
Thx
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 30 Apr 2020 09:15:39 -0400

You 9:15 is the small group about back to facilities.
I'm on
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 30 Apr 2020 13:36:59 -0400

I think we should do a press release on umbrella EUA and first NCI validation.
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.
I have had evening calls with the Comms team and Ariand about this rollout. It's coming together. Will make sure it's simple and understandable.
Liked "I think we should do a press release on umbrella EUA and first NCI validation."
Kennedy was like a dog with a bone on DPA. You handled well.
Thx
From: Keagan Lenihan
To: Stephen Hahn
Date: Fri, 01 May 2020 17:04:13 -0400

QIRA is pushing back on me. I have engaged Joe, but might need your help.
Serology policy cleared WH. So no need to Thanks.
Great. Can it be sent to me?
Will have Lauren Roth
Thx
They are cleaning up edits and will send you a clean copy.
2020-05-02 21:16:15 UTC: Messages ->

From: Stephen Hahn
To: Keagan Lenihan
Date: Sat, 02 May 2020 17:16:15 -0400

Thx
Sir, I have a serology Comms rollout call at 9:30. Want to chat after to run through calendar?
Sorry, I have a 10 am call. Call after that?
From: Keagan Lenihan
To: Stephen Hahn
Date: Sun, 03 May 2020 09:55:31 -0400

Yep
Seems to be a big disconnect on allocation and distribution of Remi. Just emailed Admiral P for info.
Still scrambling this am on distribution. Trying to figure it out.
Ugh
Why?
No one or has the expertise in house. FEMA and ASPR set up to fail here.
Would have been better.
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 04 May 2020 08:39:31 -0400

Ok
How did you find out about the loose ends?
From: Keagan Lenihan
To: Stephen Hahn
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...
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 04 May 2020 08:41:41 -0400

Wasn’t this always
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 04 May 2020 08:42:15 -0400

ASPR doesn't have clinical or ethical expertise with this drug or type of therapy.
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 04 May 2020 08:42:33 -0400

Company doesn't want to allocate either...
Ok I get it. But we'll also need Deb B's input
Exactly
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 04 May 2020 08:49:37 -0400

Do you
Not yet.
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 04 May 2020 08:51:04 -0400

I might [REDACTED] Is that ok?
Is the Whitaker/Birx/you call one that should include?
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 04 May 2020 10:54:49 -0400

Just Scott
She will only give us one 15 min window and Scott is requesting Dx. Should I let
Just have the 3 of you on the call?
APHL wants to keep the call in hopes you can join.
Jeff will manage if you can't.
Abbott test: It was submitted and they did not test enough lay users or collect sufficient fingersticks.
From: Keagan Lenihan
To: Stephen Hahn
Date: Tue, 05 May 2020 19:07:51 -0400

6th question down
Thx
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 06 May 2020 18:40:37 -0400

Admiral P was He confirmed he was ok with that?
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 06 May 2020 18:40:57 -0400

The department is
From: Keagan Lenihan
To: Stephen Hahn
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.
They want you to call Meadows on it too
Reminder- serology call
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<td>To:</td>
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<td>Date:</td>
<td>Thu, 07 May 2020 10:13:05 -0400</td>
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Ok
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 07 May 2020 12:49:17 -0400

1:30 Remdesivir call with Docs and HHS.
Yes sir.
Didn't make it on agenda, but I think talking about (b)(5) with Hargan is a good idea. His office oversees ASA.
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.
I think so but will ask
Thanks.
Heidi sending all hands on quarantine to you now.
From: Keagan Lenihan
To: Stephen Hahn
Date: Sun, 10 May 2020 17:23:59 -0400

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<th>Stephen Hahn</th>
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Sorry, dropped call. You good?
I am good. You have what you need for HELP?
Talked to Amy about data and Meadows. She is happy to NYS data being published in JAMA today
2020-05-11 13:03:43 UTC: Messages -> Messages

From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 11 May 2020 09:03:43 -0400

Liked “I am good. You have what you need for HELP?”
Everything she sees...
For real???? NYS data?
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 11 May 2020 09:04:26 -0400

Yes. That’s what she said. Want a call with...
He wants to know about our efforts on outpatient usage
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 11 May 2020 09:04:34 -0400

Liked â€œYes. Thatâ€™s what she said. Want a call with
The folks that did the NYS data also doing outpatient, but she doesn't expect results in the next few days.
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.
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 11 May 2020 14:34:11 -0400

How many PCR EUAs have been authorized?
Let me check
79 pcr (commercial and Idt). 12 serology. 1 antigen.
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 11 May 2020 14:47:13 -0400

Do you want to discuss
Do we need to flag the fact?
Probably although we weren't involved in the decision.
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Hearing a bit brutal today
Yep.
What is the agenda item 'coronavirus?'
I think PM is suppose to give vaccine update, Jim on inspections and Roundtable.
Not sure what Coronavirus is.
What do you need?
Yes I'm good for WHTF
Ok. Thanks. Is JW joining?
WHTF got moved to 3pm
Your background at the hearing was trending on Twitter today. Very “heavenly”. Pretty funny.
Still on? You have Mayo CEO call at 4:45
He just wants to provide you an update about a Thermo Fisher announcement.
I can move it if you need me to.

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

[b)(5)
After WHTF they want to do a quick prep call and then have you speak with reporter.
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 13 May 2020 16:12:20 -0400

FDA issued an EUA for these specific drugs: (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.
Let me know when you can chat with them.
Do you want call with Mark from TF this week?
Yes please
Do you know what the 5 pm meeting is about?
Let me check
For 5pm call:
Dr. Disbrow was asked to convene this group to present the plan for the candidate. Slide will be coming shortly.
Ok thx
Joining the 4?
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 14 May 2020 16:04:00 -0400

With Mark from Thermo Fisher?
Can you hold on please?
Yes. Heard from Judy.
So you can just walk in and get tested? Don't need an appointment?
Peter and JW are all set for tomorrow and will be there.
From: Stephen Hahn
To: Keagan Lenihan
Date: Fri, 15 May 2020 06:24:53 -0400

Multiple questions about: (b)(5)
Ok. Thx.
From: Keagan Lenihan
To: Stephen Hahn
Date: Fri, 15 May 2020 06:35:56 -0400

On (b)(5) Got it.
And how it could be used by WH
Just calling you about Abbott test. AMA has questions
Do you have access to the NIOSH list for masks?
I don't think so, but can ask.
Didn't you pass it along to FEMA?
Sent them what we were pulling I think. Let me look. Will send shortly.
That's what I meant, sorry
From: Keagan Lenihan
To: Stephen Hahn
Date: Sat, 16 May 2020 09:01:18 -0400

Gotcha. Hold one sec
Looking for a company called (b)(4)
Just emailed you list. Didn't see it on there. Let me look for NIOSH and non-NIOSH approved masks.
From: Stephen Hahn  
To: Keagan Lenihan  
Date: Sat, 16 May 2020 09:04:05 -0400

From meadows to Alex
Ok
Let me check with Suzanne.
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Just forwarded you email from Suzanne. She said she downloaded with Jeff so guessing he will call you too.
Thx
| From:     | Keagan Lenihan               |
| To:       | Stephen Hahn                 |
| Date:     | Sat, 16 May 2020 09:52:31 -0400 |

Emails in your inbox

Suzanne team pulling together review today.
From: Keagan Lenihan
To: Stephen Hahn
Date: Sat, 16 May 2020 14:20:21 -0400

Here is the story, working on getting you talkers.
OMA has been on the phone with the HHS press team working on prep materials for AMA.

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</table>
Ok. We still have the underlying issue to deal with
Yep
Can you put that issue on the agenda of our next call together?
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 18 May 2020 10:49:16 -0400

Fred Turner, CEO of Curative cell#
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 18 May 2020 10:49:34 -0400

I spoke with Jeff and we agree...
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 18 May 2020 10:50:59 -0400

You should call and say... They should expect to hear from CDRH today.
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)
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Do you want us to set up a call or just direct dial him yourself?
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I'll call
Ok
Anand said he just sent you a note on HCQ Comms
Ok
Howard Zucker called the front office line for you. Can you give him a call after CD call?
From: Stephen Hahn (b)(6) messages
To: Keagan Lenihan (b)(6) messages
Date: Tue, 19 May 2020 09:40:48 -0400

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**Final note:**
Yes
Thx
How about for AEG: MWF with Wednesday being at 4 pm?
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Works for me. Any concerns with WHTF?
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No
I will talk to Denise.
We can't continue to be held hostage by the lack of clarity.
Totally agree.
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 19 May 2020 13:02:53 -0400

Ok
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?
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 19 May 2020 13:17:28 -0400

 Depends on the topic
Who are Abel and Barton?
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.
Think they are from DoD
Oh ok, that's fine
Ok
Oh, perfect. Thx.
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 19 May 2020 13:45:19 -0400

Looks like the Harrison call is tomorrow at 4
Yes. They moved to tomorrow.
Liked Yes. They moved to tomorrow.
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.
Great
We have Brian Harrison tomorrow during the time we were going to move AEG and you have AMA meeting at 5.
Shook loose MOU. Moving forward.
Excellent. You are terrific
Team effort. Thx.
Great
Did you get in touch with Henry from Sorrento? Or did you want us to set up a call.
Also, Jeff just sent list of serology tests coming off to your email.
Bill gates meeting: the request is to discuss vaccine development, as well as data around both vaccines and therapeutics.
Do you want me to
YES PLEASE
Will do.
From: Keagan Lenihan
To: Stephen Hahn
Date: Fri, 22 May 2020 12:54:16 -0400

Looks like
Ok
Stacy was ______ (b)(5) _______ Do you need anything since the discussion is vaccines and therapeutics.

Do you want ______ (b)(5) _______
Appearently, the call he had with the Dept about testing he wasn't very pleasant.
I'll do it alone. They don't need the hassle
Ok.
From: Keagan Lenihan  
To: Stephen Hahn  
Date: Fri, 22 May 2020 13:47:41 -0400

Sir, the 3pm is follow up with OCC and Anand on [redacted] and also Stacy and Anand need to discuss some [redacted]
Back to offices update?
Sounds good.
WHTF likely to be Tuesday and Thursday. Can we move...
Will ask Janice.
Thx
FYI- JW sounds like she is really struggling with OWS. Seems like it's a cluster.
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 27 May 2020 13:09:06 -0400

You wanted to do Gates call solo, right?
From: Stephen Hahn
To: Keagan Lenihan
Date: Wed, 27 May 2020 13:09:19 -0400

Right
Thx
From: Stephen Hahn
To: Keagan Lenihan
Date: Wed, 27 May 2020 13:10:00 -0400

When is it?
Tomorrow
From: Stephen Hahn
To: Keagan Lenihan
Date: Wed, 27 May 2020 20:27:29 -0400

Yes for Gates.
Thx
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: Keegan Lenihan *(b)(6) messages*>
Date: Thu, 28 May 2020 20:45:18 -0400

Jeff and *(b)(4)*?
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 28 May 2020 20:46:18 -0400

Can't make this up.
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Seriously?
Laughed at "Ha, Right Can't make this up."
Yep. He (b)(5) to have a response.
Ok let's talk with n AM
I am going to get CDRH, OP and OCC together to discuss. And get back to you.
Happy to discuss tomorrow.
Feedback session right
That is my understanding. Anything you need?
No specific agenda, right?
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Will send what I have.
From: Stephen Hahn
To: Keagan Lenihan
Date: Fri, 29 May 2020 09:45:17 -0400

Nope just want to understand
From: Keagan Lenihan
To: Stephen Hahn
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

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)
Isn’t that DoD’s role in all this?
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 01 Jun 2020 14:56:45 -0400

Yes
Project management and leadership
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Helpful context for your call with the general
From: Stephen Hahn  
To: Keagan Lenihan  
Date: Mon, 01 Jun 2020 14:57:19 -0400 

Liked “Helpful context for your call with the general”
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 02 Jun 2020 08:55:45 -0400

And add to CDRH agenda: development of
Will do.
Thx
From: Keagan Lenihan
To: Stephen Hahn
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.
Joining recovery and review?
Yep. I emailed OP about (b)(5) Sounds like Anand is working similar
Jeff and I need to lay eyes on it
From: Keagan Lenihan  
To: Stephen Hahn  
Date: Tue, 02 Jun 2020 19:29:51 -0400  

Ok.
It's with Jeff. He is asking for more time.
I just asked HHS for more time.
Yes, give him the time he needs
Deb Birx is aware of our review
Ok. Pushing. Will...
Got Jeff till 2pm tomorrow, which he said ok to. Pls provide your feedback before 2 if you can. Thanks.
Wow, the Secretary this AM. I'm concerned he's on fire
Uh oh. On testing?
In general, he's trying to reassert control but has trouble treating all of us adults.
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 03 Jun 2020 09:04:48 -0400

Not helpful
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 03 Jun 2020 10:28:09 -0400

Anything else you want to discuss?
Back to office update?
Just to double check, with yours and Jeff’s edits to the document we are ok to concur with this document?
I am just double check with Jeff
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<td>Date:</td>
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Ok
Did he get back to you?
I have to let them know by noon.
He sent me his comments but didn't answer the concur question. Can you query him?
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 03 Jun 2020 11:54:03 -0400

Yes
From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 03 Jun 2020 12:00:01 -0400

From Jeff- Fine to send my comments. Consider them technical comments.
Do you concur?
From: Stephen Hahn
To: Keagan Lenihan
Date: Wed, 03 Jun 2020 12:00:43 -0400

Concur
Thx
Do you want to chat vaccine email with Anand and I now?
2020-06-04 16:53:15 UTC: Messages -> Messages

From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 04 Jun 2020 12:53:15 -0400

Any quick updates at beginning of CD call today? Maybe mentioning...
I think I'll hold off on
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Ok
Curious how much HCQ ASPR still has under the EUA. I will check.
It was a good call until we started talking about HQ
Uh oh.
Finalizing current rule and working like crazy on COVID
Any update on the CDC guidance?
Lowell and Lauren didn't know what it was. Have an email into CDRH.
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.
Will call Anna.
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Anna didn’t know and hasn’t seen. I am calling Anand now.
Will set up a call for us to work through fixing on our end.
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.
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 09 Jun 2020 08:44:39 -0400

Testing guidance
It's not for farm workers is it?
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 09 Jun 2020 08:55:16 -0400

No
From: Keagan Lenihan
To: Stephen Hahn
Date: Tue, 09 Jun 2020 08:56:46 -0400

From Tim Stenzel:
Not sure if this is about reporting results of testing. Anyway
No one seems to know what the specific guidance is.
The data are unlikely to be perfect ever
Right. And every state is going to be different. Seems like almost impossible to track.
We should be good on CDC guidance now. CDRH is good with language CMS just sent.
From: Stephen Hahn
To: Keagan Lenihan
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."
You can give AMA a heads up on Remdesivir and CQ. Just got the all clear from Patrizia. Likely Friday.
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Patrizia sent us an explanation email. Make sure you tell him it's CCI.
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 11 Jun 2020 10:46:13 -0400

I am on the call, Patrizia and Center are comfortable.
These Comms calls are super strange.
It's the same time as the JW plasma call, but to your point earlier you probably don't need to join.
Liked "It's the same time as the JW plasma call, but to your point earlier you probably don't need to join. "

From: Stephen Hahn
To: Keagan Lenihan
Date: Thu, 11 Jun 2020 12:23:26 -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

Thx

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.

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

Thank you for your attention to this matter and I look forward to hearing from you in the near future.

Sincerely,

Michael McCaul
From: Keagan Lenihan
To: Stephen Hahn
Date: Sun, 14 Jun 2020 07:43:51 -0400

Do you know the product name?
I am sure Colin will remember. Let me touch base with him and Karas and I will get back to you.
Thank you
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From: Stephen Hahn
To: Keagan Lenihan
Date: Sun, 14 Jun 2020 07:49:52 -0400
(b)(4)
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(b)(4)
I'll respond
From: Keagan Lenihan
To: Stephen Hahn
Date: Sun, 14 Jun 2020 10:27:35 -0400

Thx
Congressman,

I do have follow up for you and have learned that (b)(4)
how you would like to proceed.

Steve
We need to
Yes sir
Ok. Can we chat for 2 mins on EUA?